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#### ABSTRACT

This document, which is intended to serve as a guide for workforce preparation program providers, details the Illinois Occupational Skill Standards for clinical laboratory occupations programs. The document begins with a brief overview of the Illinois perspective on occupational skill standards and credentialing, the process used to develop the skill standards, and assumptions underlying the standards. Presented next are skill standards for each of 107 tasks typically performed by individuals employed in clinical laboratories. Each skill standard statement contains the following components: (1) a job summary; (2) the actual skill standard (including the conditions of performance, work to be performed, and performance criteria); (3) performance elements and assessment criteria; and (4) a recommended assessment and credentialing approach. The standards are grouped into the following categories: general laboratory skills; test management; body fluids; hematology; coagulation/hemostasis; microbiology; immunology; immunohematology and transfusion medicine; and chemistry. Appended are the following: glossary; lists of Illinois Occupational Skill Standards and Credentialing Council, Health and Social Services Subcouncil, and Clinical Laboratory Science/Biotechnology Cluster Standards Development Committee members; Health and Social Services Subcouncil Clinical Laboratory



Science/Biotechnology Cluster Recognition Proposal; and list of workplace skills. (MN)



# ILLINOIS OCCUPATIONAL SKILL STANDARDS

## CLINICAL LABORATORY

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## ILLINOIS OCCUPATIONAL SKILL STANDARDS

## CLINICAL LABORATORY SCIENCE/BIOTECHNOLOGY CLUSTER

Endorsed for Illinois
by the
Illinois Occupational Skill Standards and
Credentialing Council



#### MESSAGE TO ILLINOIS CITIZENS

#### Dear Citizens of Illinois:

Preparing youth and adults to enter the workforce and to be able to contribute to society throughout their lives is critical to the economy of Illinois. Public and private interest in establishing national and state systems of industry-driven skill standards and credentials is growing in the United States, especially for occupations that require less than a four-year college degree. This interest stems from the understanding that the United States will increasingly compete internationally and the need to increase the skills and productivity of the front-line workforce. The major purposes of skill standards and credentialing systems are to promote education and training investment and ensure that this education and training enable students and workers to meet industry standards that are benchmarked to our major international competitors.

The Illinois Occupational Skill Standards and Credentialing Council (IOSSCC) has been working with industry subcouncils, the Illinois State Board of Education and other partnering agencies to adopt, adapt and/or develop skill standards for high-demand occupations. This document represents the work of the Health and Social Services Subcouncil and the associated standards development committee. Through this collaborative effort, skill standards products are being developed for a myriad of industries, occupational clusters and occupations. Upon completion of these products, there will be a period of feedback and comment from business, industry and labor representatives, as well as educators.

These documents will serve as guides to workforce preparation program providers to define content for their programs and to employers to establish the skills and standards necessary for job acquisition. These standards will also serve as a mechanism for communication among education, business, industry and labor.

We encourage you to review these standards and share your comments. This effort has involved a great many people from business, industry and labor. Comments regarding their usefulness in curriculum and assessment design, as well as your needs for inservice and technical assistance in their implementation, are critical to our efforts to move forward and improve the documents. A feedback instrument is included with this document.

Questions concerning this document may be directed to:

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We look forward to your comments.

Sincerely,

The Members of the IOSSCC



#### THE ILLINOIS PERSPECTIVE

The Illinois Occupational Skill Standards and Credentialing Council (IOSSCC) endorses occupational skill standards and credentialing systems for occupations that (a) require basic workplace skills and technical training, (b) provide a large number of jobs with either moderate or high earnings, and (c) provide career advancement opportunities to related occupations with moderate or high earnings. The nine-member Council was established by the Occupational Skill Standards Act (PA 87-1210). The council, representing business, industry and labor and working with the Illinois State Board of Education in partnership with the Illinois Community College Board, Illinois Board of Higher Education, Illinois Department of Employment Security and Illinois Department of Commerce and Community Affairs, has created a common vision for workforce development in Illinois.

#### Vision

It is the vision of the IOSSCC to develop a statewide system of industry-defined and recognized skill standards and credentials for all major skilled occupations providing strong employment and earnings opportunities in Illinois. Information related to occupational employment and earning opportunities is determined by the Illinois Occupational Information Coordinating Committee (IOICC) in cooperation with business and industry.

#### Subcouncils and Standards Development Committees

The Council developed industry subcouncils (representing all major industries in Illinois) to review, approve and promote occupational skill standards and credentialing systems. In cooperation with organizations such as the Illinois Chamber of Commerce, the Illinois AFL-CIO, the Illinois Manufacturers' Association and others, the Council established the first five subcouncils in 1995—Agricultural and Natural Resources, Manufacturing, Health and Social Services, Hospitality, and Business and Administrative/Information Services.

The remaining subcouncils include Applied Science and Engineering Services; Legal and Protective Services; Transportation, Distribution and Logistics; Educational Services; Financial Services; Marketing and Retail Trade; Communications; Construction; and Energy and Utilities.

The Standards Development Committees, composed of business, labor and education representatives, are experts in the related occupational cluster and work with the product developer to

- · develop or validate occupational skill standards,
- identify related academic skills,
- · develop or review assessment or credentialing approaches, and
- · recommend endorsement of the standards and credentialing system to the industry subcouncil.

#### **Expected Benefits for Employers, Educators, Students and Workers**

Occupational skill standards and credentialing systems are being developed and promoted by the IOSSCC to improve Illinois' competitiveness. Such standards and credentialing systems provide a common language for employers, workers, students and education and training providers to communicate skill requirements and quality expectations for all major industry and occupational areas.

#### For Employers, skill standards will

- · Improve employee recruitment and retention by more clearly identifying skill requirements,
- · Encourage improved responsiveness and performance of education and training providers,
- · Enlarge the pool of skilled workers,
- · Focus attention on the importance of training investment.



#### For Education and Training Providers, skill standards will

- · Provide information on all major industries and occupations,
- · Contribute to program and curriculum development,
- · Strengthen relationships between educators and training providers,
- · Improve career planning.

#### For Students and Workers, skill standards will

- Foster better decision making concerning careers and the training necessary to acquire well-paying jobs,
- · Allow more effective communication with employers about what they know and can do,
- · Allow more effective work with employers in career development and skill upgrading.

#### **IOSSCC Requirements for Occupational Skill Standards**

Any occupational skill standards and credentialing system seeking IOSSCC endorsement must

- represent an occupation or occupational cluster which meets the criteria for IOSSCC endorsement:
- address both content and performance standards for critical work functions and activities for an occupation or occupational area;
- ensure formal validation and endorsement by a representative group of employers and workers within an industry:
- provide for review, modification and revalidation by an industry group a minimum of once every five years;
- award credentials based on assessment approaches that are supported and endorsed by the industry and consistent with nationally recognized guidelines for validity and reliability;
- · provide widespread access and information to the general public in Illinois;
- include marketing and promotion by the industry in cooperation with the partner state agencies.

#### **Definitions and Endorsement Criteria**

The definitions and endorsement criteria are designed to promote the integration of existing and future industry-recognized standards, as well as the integration of the Illinois academic and occupational skill standards. Because all skill standards must address the critical work functions and activities for an occupation or industry/occupational area, the Council further defined three major components:

- Conditions of Performance: The information, tools, equipment and other resources provided to a person for a work performance.
- · Statement of Work: A description of the work to be performed by a person.
- Performance Criteria: The criteria used to determine the required level of performance. These criteria could include product characteristics (e.g., accuracy levels, appearance), process or procedural requirements (e.g., safety, standard professional procedures) and time and resource requirements. The IOSSCC also requires performance criteria to be further specified by detailed individual performance elements and assessment criteria.

The IOSSCC is currently working with the Illinois State Board of Education and other state agencies to integrate the occupational standards with the Illinois Learning Standards which describe what students should know and be able to do as a result of their education. The Council is also working to integrate workplace skills—problem solving, critical thinking, teamwork, etc.—with both the Learning Standards and the Occupational Skill Standards.



#### The Illinois Model

Illinois Occupational Skill Standards describe what people should know and be able to do and how well these skills and knowledge will be demonstrated in an occupational setting. They focus on the most critical work performances for an occupation or occupational area. As seen in the following model, Illinois Occupational Skill Standards contain at least these areas:

- Performance Area
- Performance Skill
- Skill Standard
- Performance Elements and Assessment Criteria

The Assessment and Credentialing Approach section may also be included at the direction of the individual standards development committee.

Illinois Occupational Skill Standards also carry a coding at the top of each page identifying the state, fiscal year in which standards were endorsed, subcouncil abbreviation, cluster abbreviation and standard number. For example, the twenty-fifth skill standard in the Clinical Laboratory Science/Biotechnology Cluster, which has been developed by the Health and Social Services Subcouncil, would carry the following coding: IL.98.HSS.CL.25

A model for Illinois Occupational Skill Standards showing the placement of the coding and providing a description of each area within a standard is contained on the following page.



AND BEGINS WITH AN ACTION VERB.

#### PERFORMANCE AREA

#### SKILL STANDARD

#### CONDITIONS OF PERFORMANCE

Includes all information, tools, equipment and other resources provided to the learner for performing the work.

#### **WORK TO BE PERFORMED**

Provides an overview of the performance with the major elements or steps being described under Performance Elements and Assessment Criteria.

#### PERFORMANCE CRITERIA

Includes product characteristics (e.g., accuracy levels, appearance) and/or process or procedure requirements (e.g., safety requirements). Time limits, rates and/or speeds are specified in the Performance Criteria.

#### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Statement of the major elements, components or steps of the overall performance and the assessment criteria for determining successful performance. Includes all major tasks, the knowledge to be demonstrated and specific assessment criteria.

#### ASSESSMENT AND CREDENTIALING APPROACH

Optional statement of suggested assessment approaches for the performance which also refers to existing assessment and credentialing systems.



#### **DEVELOPMENTAL PROCESS**

Given the emerging and diverging industry in biotechnology and clinical laboratory sciences, the Health and Social Services Subcouncil paved the way for the development of skill standards describing laboratory practice through the technician or associate degree level of practice. Additional skills associated with the baccalaureate-prepared clinical laboratory scientist were not addressed in this project. This cluster meets the criteria established by the Council for performance skill standard development, education and training requirements, employment opportunities, earnings potential and/or career opportunities. The careers identified in the clinical laboratory sciences/biotechnology cluster begin with the phlebotomist and laboratory assistant through the clinical/medical laboratory technician occupations. A product developer who had both experience with articulation initiatives and knowledge of current laboratory practices began with the process of performance skill identification. Given the range of skills within biotechnology and the clinical laboratory sciences, the product developer prepared an outline and an organizational framework designed to address the major skills expected in the workplace. The framework addresses skill requirements common to working laboratories throughout the biotechnology and clinical/medical industries.

Job descriptions; professional practice descriptions from the National Accrediting Agency for Clinical Laboratory Sciences; content outlines from the Board of Registry, American Society for Clinical Pathology and the National Certification Agency for Medical Laboratory Personnel, Inc.; and practice standards as published by the National Committee on Clinical Laboratory Standards were all consulted in the selection and development of each skill standard. In addition, the development of the skill standards adhered to requirements of practice and regulations promulgated under the Clinical Laboratory Improvement Amendments of 1988 and as published in the Federal Register, February, 1992, Part 493, in particular regarding competency assessment protocols and parameters for proficiency testing. These skill standards are referenced to the Illinois Clinical Laboratory Sciences Articulation Model which was developed under the authority of the Illinois Board of Higher Education, the Illinois Community College Board and the Illinois State Board of Education.

A standards development committee composed of educators and managers at all levels, both public and private, within the cluster was convened. The framework, initial outline and matrix were presented to the standards development committee for review, revisions, adjustment and validation. The committee met and communicated over a period of approximately eighteen months to develop a master framework for skill description, criteria and assessment that would become useful as a competency assessment tool in the world of work as well as performance criteria for educational programs. The theory is that graduated demonstration of the skills as described in the standards would find acceptance and reasonable transition into positions of employment.

Performance elements and assessment criteria were developed using standard references and proficiency testing requirements described in the rules and regulations promulgated under the Clinical Laboratory Improvements Amendments of 1988 and the College of American Pathology Proficiency Programs. The skill standards begin with general laboratory skills to include basic laboratory operations and test management to include specimen/sample selection, collection, labeling and transport. The remainder of the skill standards represent more traditional clinical laboratory testing topics, to include hematology, chemistry, coagulation, microbiology, immunology and immunohematology. Each skill standard includes requirements to comply with the Occupational Safety and Health Administration Standards and to demonstrate the use of personal protective equipment. Each skill standard addresses the segregation, handling, recycling and disposal of chemical, biohazardous and/or infectious waste.

These skill standards may form the basis of instructional content for secondary, postsecondary and adult occupational training programs. Skill standards may be selected, taught and assessed in relation to each institution's or facility's philosophy, always maintaining a respect for safety, client rights, and infection control. The criteria for assessment of each skill standard is in behavioral terms. As such, they serve as an evaluation tool and a workplace guide but are not a prescription for any entire curriculum.



A complete set of skill standards statements was provided to the Subcouncil. At the recommendation of the Subcouncil, copies of the performance skill standards were distributed for further review by a selected health care community. The Subcouncil also reviewed the material in depth. Comments submitted by members of the Subcouncil and those requested from outside reviewers have been integrated into the final product. A statement of assumptions accompanies this document to provide context for the standards document.



## ASSUMPTIONS FOR CLINICAL LABORATORY SCIENCE/BIOTECHNOLOGY CLUSTER STANDARDS

#### Skill standards statements assume:

- Workplace skills (employability skills) are expected of all learners. Socialization skills needed for work are related to the lifelong career experience and are not solely a part of the initial schooling process. These are not included with this set of standards.
- 2. Specific policies and procedures of the worksite will be made known to the learner and will be followed.
- 3. Time elements outlined for the skill standards result from the experience and consideration of the panel of experts who made up the standards development committee.
- 4. Skills will progress from simple to complex. Once a skill has been successfully performed, it must be incorporated into more complex skills.
- 5. Skill standards describe the skill only and do not detail the background knowledge or theory related to the particular skill base. Although the skill standard enumerates steps to successful demonstration, rote approaches to the outcomes are not prescribed.
- 6. Skill standards are selected because they meet workplace needs and are designed to meet professional standards of practice.
- 7. While appreciating that these skill standards are rooted originally in the medical/clinical laboratory sciences, the skill standards strive to incorporate more generic language that embraces transferable skills across a full range of biotechnical and laboratory skills. Language is selected to reflect this broader range of opportunities. For example, in addition to exercising the word specimen, the skill standards will use the word sample. The word sample is more commonly used in environmental, research and industrial settings.
- 8. This selection of skill standards is not intended to embrace the entire skill base or body of knowledge currently or futuristically associated with the biotechnology or laboratory science industry. Each skill standard strives to identify the steps to demonstrate the basic principles necessary to perform laboratory procedures accurately. These basic principles include the physical, chemical, electrical and morphological analysis of samples utilizing a variety of laboratory instruments and encompassing one or more methods. In the event the challenger is unsuccessful in demonstrating a skill standard, the performance and the planned remediation must be documented.
- 9. Skill standards do not replace, supersede or substitute for procedure manuals.
- Skill standards in no way supersede or take the place of certification or graduation from an accredited program of study.
- 11. All reagents and supplies are in date and have been properly stored.
- 12. Skills are identifiable, measurable standards of practice which practitioners may use to demonstrate competency to employers. Practitioners and graduates may develop portfolios of competencies to accompany them into a competitive workplace.
- 13. Skill standards are written in terms of what the challenger (practitioner/student/employee) is required to do in order to demonstrate competency.



- 14. Achieving and maintaining competency and demonstrating the standard level of proficiency to perform test procedures and report test results promptly, accurately and proficiently are the responsibilities of the challenger. Evaluating, assessing, confirming and documenting the competency of all students/personnel are necessary semiannually during the first year and annually thereafter unless test methodology or instrumentation changes. In that case, prior to reporting test results, the instructor/employer must reevalute the individual's performance using the new test methodology or instrumentation changes. When individual criteria for performance do not comply with the standards, procedures for remediation and reevaluation are the joint responsibility of the challenger and the supervisor and must be demonstrated and documented prior to reporting test results.
- 15. Skill standards are performed under conditions consistent with safe laboratory practice and conform to recognized and accepted standards of practice. Skill standards involving biologically hazardous material are performed with the participant wearing a fluid-resistant laboratory coat, gloves and other personal protective equipment.
- 16. The skill standards fit within the conceptual framework of the October 1995 Illinois Clinical Laboratory Science Articulation Model Curriculum, specifically within the competency relating to Technical Skills.
- 17. Skill standards are designed to complement the personnel competency assessment requirements of the regulations for the implementation of the Clinical Laboratory Improvement Amendments of 1988. Skill standards may be used to assess student outcomes as well as employee competencies.
- 18. In keeping with the US Code of Federal Regulations and international standards regarding current good manufacturing practices or current good laboratory practices, standard equipment, supplies and reagents intended for laboratory operations or procedures are used in the manner for which they are designed and in the manner consistent with the instructions provided by the manufacturer.



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(Continued)

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	Collect a Specimen from Wound Drainage for Culture and Sensitivity	•	•	•	•
	Collect a Specimen for Pinworm (Enterobius Vermicularis)	•	•	•	•
	Collect a Specimen for Throat Culture	•	•	•	•
BODY FLUIDS				•	
	Examine and Record the Physical Characteristics of Urine		•	•	•
	Analyze the Chemical Characteristics of Urine		•	•	•
	Examine and Record the Microscopic Characteristics of Urine Sediment		•	•	•
	Evaluate the Physiology and Composition of Spinal Fluid			•	•
	Collect and Evaluate a Fecal Sample; Test for Presence of Fecal Occult Blood		•	•	•
	Perform Qualitative Urine (Serum) Test to Detect Pregnancy		•	•	•
	Perform Seminal Fluid Analysis			•	•
	Perform Fecal Leukocyte Count			•	•
HEMATOLOGY					
	Analyze Whole Blood by Automated Particle Counter	П	•		•
	Prepare and Stain a Peripheral or Wedge Blood Smear	$\dashv$	•	•	•
	Assess White Blood Cell Differential and Recognize Pathological/Abnormal to Refer		•	•	•
	Assess Erythrocyte Morphology and Recognize Pathological/Abnormal to Refer		•	•	•
	Assess Platelet Morphology and Recognize Pathological/Abnormal to Refer	1	•	•	•
	Perform an Erythrocyte Sedimentaion Rate	$\top$	•	•	•
	Perform a Manual Reticulocyte Count	$\top$	•	•	•
	Perform Screening Solubility Test for Sickle Cell	$\exists$	•	•	•
	Perform a Microhematocrit	$\top$	•	•	•
	Perform a Manual White Blood Cell Count		•	•	•
		_		-	_



(Continued)

HEMATOLOGY (Continued)		PHLEBOTOMIST	CL ASSISTANT	CL TECHNICIAN	RI SCIENTIST
	Perform a Hemoglobin Determination by a Hemoglobin Analyzer		•	•	•
	Calculate and Correlate Erythrocyte Indices		•	•	•
	Perform a Manual Platelet Count		•	•	•
COAGULATION/HEMOSTASIS					
	Perform Test for Activated Partial Thromboplastin Time		•	•	•
	Perform Prothrombin Time Test and Calculate the International Normalized Ratio (INR)		•	•	•
	Perform Test for Fibrinogen		•	•	•
	Perform Test for Thrombin Time		•	•	•
	Perform Test for Rapid, Semiquantitative Serum Fibrin(ogen) Degradation Products (Latex Agglutination Immunoassay)		•	•	•
	Perform a Bleeding Time (Ivy) Test	•	•	•	•
MICROBIOLOGY	Demonstrate Isolation Technique; Discriminate				
	Colony Morphology				_
	Prepare, Stain and Interpret a Differential Gram Stain  Demonstrate Catalase Test to Differentiate Staphylococci and  Micrococci Species from Other Aerobic Gram-Positive Cocci			•	•
	Demonstrate Coagulase Test (Slide [Free] or Tube [Free and Bound])			•	•
	Demonstrate Oxidase Spot Test			•	
	Demonstrate the ONPG Test			•	•
	Demonstrate Bacitracin Susceptibility for the Presumptive Identification of Streptococcus Pyogenes (Group A)			•	•
	Isolate and Identify Group A Strep from Throat			•	•
IMMUNOLOGY					
	Perform Rapid Differential Absorption Test to Detect Infectious Mononucleosis		•	•	•
	Demonstrate a Titration Such as an Antistreptolysin O or A Cold Agglutinin		•	•	•
	Demonstrate a Neutralization Assay Such as Anti-DNASE	-		•	•
	Demonstrate a Ligand Assay			•	•
	Demonstrate an Immunofluorescence Assay	T	Т	•	•



(Continued)

IMMUNOLOGY (Continued)		PHLEBOTOMIST	CL ASSISTANT	CL TECHNICIAN	CL SCIENTIST
	Demonstrate an Agglutination Assay Such as a Rapid Slide Test for Rheumatoid Factor		•	•	
	Demonstrate Flocculation Test Such as the VDRL or the Rapid Plasma Reagin Test for Syphilis			•	•
	Demonstrate an Electrophoretic Procedure		•	•	•
	Demonstrate a Radial Immunodiffusion		•	•	•

#### IMMUNOHEMATOLOGY AND TRANSFUSION MEDICINE

	T			
Select Suitable Donors			•	•
Collect Single Unit of Blood from Donor			•	•
Process Donor Blood			•	•
Harvest Components from Single-Donor Units			•	•
Perform ABO Typing by Rapid Slide Test		•	•	•
Perform ABO Typing by Rapid Tube Test (Forward and Reverse)		•	•	•
Perform Antigen Typing for Weak D		•	•	•
Perform Red Cell Antigen Typing (Kell, Kidd, Duffy, Lewis, Etc.)			•	•
Perform an Antibody Screen and Identification			•	•
Perform Routine Pretransfusion Compatability Testing			•	•
Perform and Interpret Direct Antiglobulin Testing; Investigate Positive Direct Antiglobulin Test Due to Autoimmune Hemolytic Anemia			•	•
Perform Routine Testing for Administration of Rh Immune Globulin			•	•
Investigate Suspected Transfusion Reactions			•	•
Investigate Hemolytic Disease of the Newborn		寸	•	•
Issue Blood and Blood Products for Infusion			•	•

#### CHEMISTRY

Perform Test for Electrolytes (Sodium, Cloride and Potassium)	•	•	•
Perform Tests for Enzymes (Alanine Aminotransferase, Alkaline Phosphatase, Amylase, Aspartate Aminotransferase, Creatine Kinase, Lactate Dehydrogenase and Gammagluta Transerase)	•	•	•
Perform Test of Therapeutic Drug Monitoring	•	•	•



CHEMISTRY	(Continued)		PHLEBOTOMIST	CL ASSISTANT	CL TECHNICIAN	CL SCIENTIST
		Perform Test for Uric Acid		•	•	•
,		Perform Test for Urea Nitrogen		•	•	•
		Perform Test for Creatinine		•	•	•
		Perform Test for Protein		•	•	•
		Perform Test for Albumin		•	•	•
		Perform Test for Glucose		•	•	•
		Perform Screening Test for Drugs of Abuse (Phencyclidine, Benzodiazepines, Cocaine [Benzoyl Ecgonine], Amphetamines, THC, Opiates, Barbiturates, Tricyclic Antidepressants)		•	•	•
		Perform Test for Blood Gases		•	•	•
		Measure Blood Cholesterol - Manual Method	$\Box$	•	•	•
		Perform Automated Methods for Lipid Analysis: Cholesterol to Include HDL and Triglycerides		•	•	•
		Perform Tests of the Endocrine System		•	•	•



#### **GENERAL LABORATORY SKILLS**

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Pipetting aids

Selection of volumetric or graduated, calibrated, clean pipettes from which to choose

Appropriate manual or automatic pipette

OSHA-recommended personal protective equipment

Biohazard container

#### **WORK TO BE PERFORMED**

Demonstrate the transfer of liquids using a volumetric, a graduated, a serological, a micro and a repeating pipette. Demonstrate both "to contain" and "to deliver" technique. Demonstrate the proper disposal of both the disposable pipette and the glass reusable pipette and disposable pipette tip.

#### **PERFORMANCE CRITERIA**

Select the correct pipette and pipetting aid for the transfer of liquid correctly with 100% accuracy.

#### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

2. Assemble a selection of pipettes, both automatic and manual, and pipetting aids. Demonstrate the required inspection and/or preventive maintenance, if any, for each device.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

3. Read the pipetting challenge noting the volume of liquid transfer and the accuracy requirements.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 4. Select the most appropriate pipette for the liquid transfer.
- 5. Charge the pipette, bringing liquid slightly past the desired level and then setting the meniscus on the graduated mark. Wipe the tip. Deliver the liquid either to "deliver" or to "contain."



#### Record, Evaluate and Report Results:

6. Record the results of each pipetting exercise as requested.

Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Clean or dispose of pipette. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

#### **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Pass a written test to define "to deliver" and "to contain" and to differentiate the grades of pipettes and the types of pipettes (volumetric, graduated, serological, micropipette, etc.) with a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

For five different transfer tasks, demonstrate use of the appropriate pipetting device ranging from a manual pipette with a pipette aid, a micropipette and an automatic pipetting device (including volumetric and graduated pipettes) to contain and to deliver.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Pipetted samples must match target values with +98% accuracy.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Complete required documentation.

#### Demonstrate Problem-Solving Skills:

Example: After filling the pipette and setting the meniscus on the correct graduated mark, a tiny air bubble floats up the stem of the pipette. What action is required?



#### **GENERAL LABORATORY SKILLS**

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Calibrated, working centrifuge OSHA-recommended personal protective equipment Biohazard container

#### **WORK TO BE PERFORMED**

Operate the centrifuge safely with lid closed, balance the centrifuge and select the correct revolutions per minute and time for the specific separation task.

#### **PERFORMANCE CRITERIA**

Complete the separation exercises in twenty minutes with a balanced centrifuge creating a minimum of aerosols 100% of the time.

### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

- 2. Read the separation requirements for the exercise, i.e., urine from sediment or red blood cells from plasma or serum. Select and/or inspect the container.
- 3. Select the appropriate speed and time for the separation task.
- 4. Balance the centrifuge.
- 5. Engage safety devices to reduce aerosols.
- 6. Close the lid of the centrifuge and lock. Engage the motor. Allow allotted time to pass.
- 7. Let the centrifuge come to a complete stop. Open the centrifuge and carefully disengage any aerosol reducing devices. Remove samples.
- 8. Wipe up any spills or evidence of aerosols.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

9. Look for hemolysis of serum or plasma or for any other quality of the specimen that might require recentrifugation or recollection.

## Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

10. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.



#### **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

State the purpose of centrifugation, define rpm (revolutions per minute), identify parts, etc. Competence is demonstrated by a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the correct use of the centrifuge given a selection of separation tasks. Successful demonstration requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Document maintenance and complete other logs as required by procedure.

#### Demonstrate Problem-Solving Skills:

Example: The centrifuge is loaded and the lid is closed. The rpms and timer are set. At approximately 750 rpms, the centrifuge begins to wobble. State the next course of action.



#### **GENERAL LABORATORY SKILLS**

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Operational microscope

Selection of demonstration slides to be viewed at low power (10 x), high power (40 x) and oil immersion

Identified and labeled microscope parts using a diagram or an actual scope OSHA-recommended personal protective equipment

Biohazard container

#### **WORK TO BE PERFORMED**

Demonstrate the maintenance and operation of a bright field microscope.

#### PERFORMANCE CRITERIA

The steps of the following procedure shall be demonstrated in five minutes.

#### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

- 2. Turn on microscope and assemble supplies.
- 3. Clean the oculars and objectives.
- 4. Maximize working distance with the use of coarse adjustment.
- 5. Raise the condenser as far as possible.
- 6. Rotate the low power objective into position so that it is directly over the opening in the stage.
- 7. Open the diaphragm(s) until maximum light comes up through the condenser.
- 8. Focus the condenser.
- 9. Position low power objective at the proper working distance for initial focusing.
- 10. Place slide on stage (specimen side up) and secure.
- 11. Look into the ocular and slowly turn the coarse adjustment in the opposite direction to raise the objective (or lower the stage) until the object on the slide comes into view.
- 12. Locate the fine adjustment.
- 13. Turn the fine adjustment to sharpen the image. If using a binocular scope, adjust the oculars for each of the eyes.
  - a. Adjust distance between oculars so that one image is seen.
  - b. Use coarse and fine adjustments to bring object into focus while looking through the right ocular with right eye.



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- c. Close the right eye, look into the left ocular with left eye and use the knurled collar on the left ocular to bring the object into sharp focus. Do not turn the coarse or fine adjustment at this time.
- d. Look into oculars with both eyes to observe that object is in clear focus. If not, repeat the procedure.
- 14. Scan the slide by either of the following methods.
  - a. Use the stage knobs to move the slide left and right and backward and forward while looking through the oculars.
  - b. Move the slide with the fingers while looking through the oculars (use this method for a microscope without a movable stage).
- 15. Rotate the high power objective into position while observing the objective and the slide to see that the objective does not strike the slide.
- 16. Look through the ocular to view the object on the slide. It should be almost in focus.
- 17. Locate the fine adjustment.
- 18. Look through the oculars and turn the fine adjustment until the object is in focus. Do not use the coarse adjustment at this time.
- 19. Scan the slide using the fine adjustment if necessary to keep the object in focus.
- 20. Rotate the oil immersion objective to the side slightly so that no objective is in position.
- 21. Place one drop of immersion oil on the portion of the slide which is directly over the condenser.
- 22. Rotate the oil immersion objective into position, being careful not to rotate the 40 x objective through the oil.
- 23. Look to see that the oil immersion objective is touching the drop of oil.
- 24. Look through the ocular and slowly turn the fine adjustment until the image is clear. Use only the fine adjustment to focus the oil immersion objective.
- 25. Scan the slide.
- 26. Rotate the low power objective into position. Do not allow the high power objective to touch the oil.
- 27. Remove the slide from the microscope stage and gently clean the oil from the slide with lens paper.
- 28. Clean the oculars, low power objective and the high power objective with lens paper.
- 29. Clean the oil immersion objective with lens paper to remove the oil.
- 30. Clean any oil from the microscope stage and condenser.
- 31. Turn off the microscope light.
- 32. Position the nosepiece in the lowest position using the coarse adjustment.
- 33. Center the stage so that it does not project from either side of the microscope.
- 34. Cover the microscope and return it to storage position.
- 35. Clean work area and return slides to storage.

### Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 36. Clean work area with disinfectant.
- 37. Remove gloves and discard into biohazard container.
- 38. Wash hands with disinfectant.



#### **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Identify parts of the microscope and describe the principles of microscope operation. Competence is demonstrated by a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the operation of a microscope under the direct observation of authorized personnel.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Report the findings of prepared slides at low power, high power and oil immersion.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Record maintenance and results as required by the procedure.

#### Demonstrate Problem-Solving Skills:

Example: When looking through the oculars, the field is black. What are the possible causes?



#### **GENERAL LABORATORY SKILLS**

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Operational spectrophotometer

Standard solution

Five solutions of unknown concentration

Diluent

Cuvettes

**Pipettes** 

Controls

OSHA-recommended personal protective equipment

Biohazard container

13 X 100 mm test tubes

Parafilm or other stopper

Pen or pencil

Graph paper

Laboratory wipes

#### **WORK TO BE PERFORMED**

Prepare and evaluate a standard curve and determine the concentration of five unknowns.

#### **PERFORMANCE CRITERIA**

The steps of the following procedure shall be demonstrated in thirty minutes. The concentration of the unknowns must be correct within  $\pm 10\%$  of known concentration.

#### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

- 2. Turn on spectrophotometer to warm up, usually for 30 minutes.
- 3. Select the wavelength that is appropriate for the chosen standard. For example, if preparing a hemoglobin standard, select a wavelength of 540 nm.
- 4. Assemble equipment and materials to include the standard solution, 13 x 100 mm test tubes, diluent (if plotting a hemoglobin standard, select Drabkin's reagent), cuvettes, parafilm or other stopper to prevent evaporation, appropriate pipettes, pen or pencil, graph paper, laboratory wipes, surface disinfectant, biohazard container, hand disinfectant, gloves and spectrophotometer.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Label test tubes for the predetermined concentrations and for the five unknowns. (If performing a standard curve for hemoglobin, start with a 20 gm/dL standard hemoglobin solution and tubes labeled as 0.0 (blank), 5.0, 10.0, 15.0 and 20.0; label the five tubes with the unknowns as A, B, C, D, E.
- 6. Reconstitute the standard according to manufacturer's instructions if in a lyophilized form.
- 7. Make dilutions of the standard. For example, if preparing a hemoglobin standard curve:
  - a. Pipette the Drabkin's reagent into the tubes

cir
0
5
0
5

b. Pipette the hemoglobin standard solution into the same tubes as follows, using a clean pipette:

Tube	mL Hemoglobin Standard
0	0
5	1.5
10	3.0
15	4.5
20	6.0

- c. Repeat pipetting sequence using unknowns.
- 8. Observe the tubes to see that each contains the same volume (6.0 mL) and mix each tube well using the parafilm or stopper to cover the top of the tube.
- 9. Transfer contents of the "0" tube to clean cuvette. Wipe prints and smudges from the cuvettes with the soft tissue and place in cuvette well of the spectrophotometer.
- 10. Cover the cuvette well and set the absorbance to zero using the control knob.
- 11. Remove the "0" cuvette from well.
- 12. Transfer contents of the "5" tube to a clean cuvette, wipe away prints, place cuvette in well and cover.
- 13. Read and record absorbance and remove cuvette from the sample well.
- 14. Repeat steps 12-13 for tubes 10, 15 and 20 and read and record the absorbance of the five unknowns.
- 15. Plot an X an Y axis selecting the correct graph paper or computer program.
- 16. Label the X axis in units of standard measured (i.e., hemoglobin) concentration: 0.0, 5.0, 10.0, 15.0, 20.0 gm/dL.
- 17. Label the Y axis in absorbance (A) units from 0-1.000 using the intervals of 0.100.
- 18. Plot the absorbencies of the standard tubes: 5, 10, 15 and 20.
- 19. Draw the best fit line through the points being sure it passes through the origin.
- 20. Using this graph, determine the concentration of the five unknown solutions.

#### Record, Evaluate and Report Results:

21. Evaluate the results of the unknowns in the context of the quality control standards, calculate and remediate or report results.



## Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 22. Disinfect and clean the equipment and return to proper storage. Dispose of used reagent and contaminated materials according to OSHA standards.
- 23. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

#### **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Pass a written test with a score of 90% or better to identify the parts of a spectrophotometer, describe the principles of operation and use Beer's law to determine the concentration of an unknown.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the construction and use of the standard curve and the operation of a spectrophotometer under the observation of authorized personnel. Competency requires 100% compliance with performance elements to include spectrophotometer maintenance and function checks.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

Evaluate controls and report the findings of unknowns. Unknowns must match target values within  $\pm 10\%$ .

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The standard curve fails to yield a straight line. What are the likely causes and what must the operator do next?



#### **GENERAL LABORATORY SKILLS**

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Refractometer

Standards

Controls

Unknowns

A procedure

OSHA-recommended personal protective equipment

Quality control charts

Log sheets

Biohazard container

#### **WORK TO BE PERFORMED**

Calibrate the refractometer and determine the specific gravity of a minimum of two controls and five different samples representing the full range of expected values.

#### PERFORMANCE CRITERIA

Demonstrate the determination of specific gravity in five minutes with 100% accuracy.

#### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

- 2. Assemble equipment, controls and samples to be tested, quality control charts and log sheets for recording results.
- 3. Calibrate the refractometer by placing one drop of deionized water on the glass plate of the refractometer and gently close. Look through the ocular and read the specific gravity. Water should read 1.000. Wipe the water from the plate. Record results.

#### Perform Procedure and Quality Control; Document and Evaluate:

4. Mix a high and low control; place a drop, one at a time, of each liquid of known specific gravity on the glass plate. Gently close the cover. Look through the ocular and read the specific gravity. Wipe the control from the plate. Rinse and dry the plate between each control and each sample. Record the results.



5. Mix the samples to be tested and place a drop onto the glass plate. Gently close the cover. Look through the ocular and read the specific gravity. Wipe the sample from the plate.

#### Record, Evaluate and Report Results:

6. Record results and evaluate in relationship to control values. If accepted, report results.

## Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 7. Clean the glass plate with disinfectant and dry with soft tissue. Do not scratch.
- 8. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

#### ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Pass written test with a score of 90% or better to define specific gravity and the physiological information relative to the specific gravity.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the determination of specific gravity of two levels of control using at least five selected samples and care for the instrument.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Unknown samples must match target values with +10%.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The specific gravity of the urine is greater than 1.035. What is the next course of action?



#### **GENERAL LABORATORY SKILLS**

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

pH meter

Set of standards

Controls

Samples (acid, basic and neutral)

Relevant reference ranges

A procedure

OSHA-recommended personal protective equipment

Charts and log sheets

Biohazard container

#### **WORK TO BE PERFORMED**

Maintain and calibrate the pH meter. Determine the pH of a minimum of two different levels of controls and five unknowns representing a full range of acid, basic and neutral samples. Record and evaluate results. Accept or reject results in context of control values and known reference ranges.

#### PERFORMANCE CRITERIA

The maintenance, calibration and determination of two controls and five unknown samples shall be completed in thirty minutes and within  $\pm 0.04$  of the target values.

#### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

2. Assemble equipment, a set of standards, unknown samples and charts and log sheets for recording results.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

Assess sample for conditions that might interfere with results such as lipemia
or hemolysis. Accept, reject or treat sample as required to prepare for
analysis.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 4. Calibrate the pH meter with a minimum of two levels of standard solutions, one of which is near the pH of the solution to be measured.
- 5. Measure the pH of a variety of samples provided following the written procedure.



#### Record, Evaluate and Report Results:

- 6. Record the results of the controls and samples. Evaluate controls as a decision element in relationship to accepting and subsequent reporting of sample results.
- 7. Upon completing the exercise, demonstrate the proper cleaning and storage of a pH electrode.

## Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

#### ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% on a written test to define pH, describe the pH electrode and the mechanism by which it measures hydrogen ion concentration and its range and uses in preparing reagents and in determining physiological acid/base status.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. These include instrument maintenance and function checks.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Determine the pH of controls and unknowns. Results must agree within  $\pm 0.04$  of the target values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: When taking the pH reading, the needle drifts and will not settle on one reading. What is the next course of action?



# **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Osmometer

Standards

Controls

Range of samples

Relevant reference ranges

A procedure

Charts and log sheets

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Calibrate the osmometer, determine the osmolarity of the samples and record results. Accept or reject results in the context of control results, sample results and the reference range for the samples provided.

## PERFORMANCE CRITERIA

The maintenance, calibration and determination of five unknown samples should be completed in twenty minutes within +10% of target values.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

- 2. Assemble equipment, a set of standards and unknown samples and charts and log sheets for recording results.
- 3. Calibrate the osmometer with a minimum of two levels of standard solutions.

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assess the condition of the sample for factors that may interfere with analysis.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Measure the osmolarity of a variety of samples provided recording the results of each.
- 6. Upon completing the exercise, demonstrate the proper cleaning and storage of an osmometer.



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### Record, Evaluate and Report Results:

7. Record the results of the controls and samples. Evaluate controls as a decision element in relationship to accepting and subsequent reporting of sample results.

# Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

# ASSESSMENT AND CREDENTIALING APPROACH

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to define osmometry; the mechanism by which it measures particles; and its chemical, physical and biological uses.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. These include instrument maintenance and function checks.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Determine the osmolarity of two controls and five unknowns. The results must agree within ±10% of the target values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

### Demonstrate Problem-Solving Skills:

Example: The osmometer has been calibrated and standardized. The controls, both the high and low values, are low. What is the next course of action?



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Standard

Calibrated laboratory balance or scale appropriate for the quantity to be weighed and for the sensitivity required

Charts and log sheets

OSHA-recommended personal protective equipment

Biohazard container

# **WORK TO BE PERFORMED**

Maintain the balance and weigh a variety of given unknown samples.

## PERFORMANCE CRITERIA

Weigh a minimum of 5 samples in 15 minutes with an accuracy of ±2% of the target value.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

- 2. Assemble equipment, a set of standards and unknown samples and charts and log sheets for recording results.
- 3. Verify the calibration of the gravimetric device using standard weights.

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assess sample for conditions that may require special containers (liquids) or other special provisions.

## Perform Procedure and Quality Control; Document and Evaluate:

- 5. Weigh the variety of known standards and unknown samples provided.
- 6. Upon completing the exercise, demonstrate the proper cleaning and storage of the gravimetric device.

### Record, Evaluate and Report Results:

7. Record the results of the different samples.

# Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.



# **ASSESSMENT AND CREDENTIALING APPROACH**

## Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to describe the principle of operation and the standard parts of gravimetric devices.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. These include instrument maintenance, function checks and the demonstration of the use of a standard balance.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Determine the weight of a minimum of five specimens. The results must agree within  $\pm 2\%$  of the target values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

### Demonstrate Problem-Solving Skills:

Example: The balance in the laboratory is accurate to 0.01 gram. The procedure calls for 575 mg of NaCl. Describe the course of action leading to the most accurate results.



# SKILL STANDARD

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Common temperature and atmospheric controlled spaces including room, refrigerators, freezers and incubators within the laboratory Accompanying log sheets
Reliable, calibrated temperature controlling devices

# **WORK TO BE PERFORMED**

Record temperature, humidity and atmospheric pressures and take corrective action when any of these recordings exceed posted limits.

# PERFORMANCE CRITERIA

Record temperature, humidity and atmospheric pressures within  $\pm 1\%$  of the target values. Review values in the context of posted limits. When recorded values exceed outer limits, take and record corrective action according to laboratory procedures.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### Perform Procedure, Document and Evaluate:

1. Open temperature controlled unit and read the temperature from the calibrated thermometer. When humidity and/or atmospheric pressure are also monitored, read the humidity and atmospheric pressure gauges.

### Record, Evaluate and Take Corrective Action as Required:

- 2. Record the temperature and/or humidity and evaluate the result in relationship to posted limits.
- 3. If the temperature or the humidity exceeds the posted limits, follow laboratory protocol for adjusting temperature or removing contents to other locations. Record and report corrective action.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better to include a description of the differences and conversions between Fahrenheit and Celsius.

## Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the correct reading of a thermometer, atmospheric pressure gauge and a humidity gauge using calibrated and certified measuring devices.



Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets and Recording and Reporting of Maintenance of Logs:

Competence is demonstrated through 95% compliance with complete documentation to include recording and evaluation of values in the context of posted limits and laboratory procedures.

## Demonstrate Problem-Solving Skills:

Example: Cultures are stored at 35° Celsius. The thermometer on the incubator reads 29° Celsius. What is the next course of action?



## **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Choice of personal protective clothing Biohazard container

## **WORK TO BE PERFORMED**

Select the fluid-resistant laboratory coat with closed neck and wrists and a face mask to protect mucous membranes of the mouth and nose.

## PERFORMANCE CRITERIA

This skill standard requires 100% compliance throughout this demonstration and in the course of demonstrating other skills.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

## Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Select the fluid-resistant laboratory coat and face mask.

### Assemble, Maintain and Monitor Equipment:

2. Inspect the coat and the mask for holes, contamination or other applicable criteria. If criteria are not met, discard the item.

#### Perform Procedure:

3. Put on the fluid-resistant laboratory coat to protect the body and extremities. Fit the face mask tightly over the nose and mouth to screen out aerosol particles that may enter the respiratory or digestive tracts.

# Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

4. After completing tasks, clean work area with disinfectant. Remove fluid-resistant laboratory coat, mask and gloves and discard into biohazard container. Wash hands with appropriate disinfectant.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test detailing the conditions under which fluid-resistant laboratory coats and fitted face masks must be worn.



### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Not applicable.

## Demonstrate Problem-Solving Skills:

Example: Upon removing blood tubes from the centrifuge, a tube breaks and spatters blood on the fluid-resistant laboratory coat. Describe the correct course of action.



## **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

Given the following:

Non-sterile, disposable gloves

Note: The use of non-sterile gloves will provide protection for the learner, the client and other personnel.

## **WORK TO BE PERFORMED**

The learner will use non-sterile gloves as a necessary precaution in care according to approved universal precautions.

## PERFORMANCE CRITERIA

The standard for use of non-sterile gloves is determined by universal precautions standards and the appropriate facility policy. Time element is not applicable.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

- 1. Determine that use of non-sterile gloves is required as a protective safety measure.
- 2. Remove gloves by grasping the outside of one glove near the cuff, with the thumb and forefinger of the other hand. Pull it off, turning it inside out while pulling.
- 3. Hook the bare thumb inside the other glove and pull it off, turning it inside out. The two gloves will be rolled together, with the side that was nearest the learner's hand on the outside.
- 4. Dispose of the soiled gloves according to facility policy.
- 5. Wash and dry hands thoroughly.

The steps of performance have been numbered to show an appropriate sequence of completing the work; however, a different sequence may be used.

# ASSESSMENT AND CREDENTIALING APPROACH

Pass Written Test of Principles:

Written tests of principles of physical care and proper use of disposable gloves.

Demonstrate Procedure/Skill under Direct Observation:

Performance of procedure for selected client.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Eye protection devices

Working condition when splashes, spray, spatter or droplets of blood, other body fluids or infectious materials may be generated Biohazard container

# **WORK TO BE PERFORMED**

Select and put on an eye protection device fitting the appliance to the face.

## PERFORMANCE CRITERIA

This skill standard requires 100% compliance throughout this procedure and in the course of demonstrating other skills.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Select the proper eye protection device.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

2. Inspect the eye protection device for holes, splatter or other contamination. Disinfect if required.

#### Perform Procedure:

3. Put on the eye protection device fitting it snugly to screen out aerosol particles.

# Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

4. After completing required tasks, clean work area with disinfectant. Remove the eye protective device, clean or disinfect as necessary. Remove other personal protective equipment and discard into biohazard container. Wash hands with disinfectant.

# ASSESSMENT AND CREDENTIALING APPROACH

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test detailing the conditions under which an eye protective device is required and what to do in the event the device fails.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Not applicable.

### Demonstrate Problem-Solving Skills:

Example: A set of goggles did not fit as tightly as recommended and urine is splattered into the eye. Describe the next course of action.



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Exposed and used needles
Pipettes or other sharps
Sharps container
OSHA-recommended personal protective equipment
Biohazard container

# **WORK TO BE PERFORMED**

Locate a biohazard sharps container and dispose of the sharp.

## PERFORMANCE CRITERIA

This skill standard requires 100% compliance throughout this procedure and in the course of demonstrating other skills.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Identify and dispose of contaminated sharps into designated, biohazard-labeled, color-coded, puncture-resistant and leakproof sharps container.

#### Record, Evaluate and Report Results:

2. Indicate how exposures to contaminated sharps are to be documented.

# Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

3. Clean work area with disinfectant. Remove gloves and other personal protective equipment and discard into biohazard container. Wash hands with disinfectant.

# ASSESSMENT AND CREDENTIALING APPROACH

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better describing the safe handling of contaminated sharps, recapping rules and prohibitions and listing devices that qualify as sharps. Items indicating post-exposure procedures are required.



#### Demonstrate Procedure/Skill under Direct Observation:

Dispose of the identified sharps into the sharps container.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation especially in the event of an exposure.

### Demonstrate Problem-Solving Skills:

Example: A practitioner receives a puncture wound with a contaminated needle. Describe the correct course of action.



## **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Different kinds of certified fume hoods and biological safety cabinets OSHA-recommended personal protective equipment Biohazard container

# **WORK TO BE PERFORMED**

Identify safety and operational features of fume hoods and biological safety cabinets and demonstrate the uses of each.

## PERFORMANCE CRITERIA

This skill standard requires 100% compliance throughout this procedure and in the course of demonstrating other laboratory-related skills.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

## Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Prepare the hood for use. Put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

2. Maintenance requires periodic checks to ensure proper air flow velocity and cleaning of the filters.

### Perform Procedure and Quality Control; Document and Evaluate:

3. Demonstrate the correct use of fume hoods and biological safety cabinets.

# Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

4. Clean work area with disinfectant. Remove gloves and other personal protective equipment and discard into biohazard container. Wash hands with disinfectant.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to identify the safety features of fume hoods and biological safety cabinets to include explanations of high efficiency particulate air (HEPA) filters, how incoming and exhausting air is handled and techniques for measuring air flow velocity.



### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Air velocity checks, filter cleaning and other maintenance must be documented.

### Demonstrate Problem-Solving Skills:

Example: On checking the air flow of the hood, the meter reads one-half the required capacity. Describe the most likely cause and course of action.



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# SKILL STANDARD

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Containers of hazardous chemicals properly labeled with hazard warnings Records of MSDS on all hazardous chemicals OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Detect the presence or release of hazardous chemicals in the work area and locate information on hazards associated with the chemicals in the work area and the location and use of appropriate protective equipment.

## PERFORMANCE CRITERIA

This skill standard requires 100% compliance throughout this exercise and in the course of demonstrating other laboratory skills.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Put on gloves and other personal protective equipment.

### Assemble and Locate Information:

- 2. Locate the Hazardous Chemicals List and the MSDS reference number.
- 3. Locate labeling information relevant to hazardous exposure to include:
  - a. Chemical or mixture with its chemical and common name
  - b. Physical and chemical characteristics of each chemical
  - c. Health hazards, signs and symptoms of exposure and medical conditions aggravated by exposure to the chemical
  - d. Primary routes of entry into the body
  - e. Published exposure limits
  - f. Carcinogenicity
  - g. Safe handling
  - h. Engineering controls, work practices and personal protective equipment required
  - i. Emergency first aid procedures
  - j. Date of preparation and revision of the latest MSDS
  - k. Name, address and telephone number of responsible party for emergency procedures



### Record, Evaluate and Report Results:

4. Document an exposure (simulated or actual).

# Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

5. As applicable, clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

# ASSESSMENT AND CREDENTIALING APPROACH

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the purpose of the OSHA Hazard Communication Standard, rules for labeling, definitions of physical and chemical hazards and use of Material Safety Data Sheets.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

### Demonstrate Problem-Solving Skills:

Example: An acid spill occurs. What is the first course of action?



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

Given the following:

Cleansing agent
Sink with running water
Paper towels
Waste container

# **WORK TO BE PERFORMED**

Wash hands, wrists (forearms) and fingernails in an aseptic manner.

## **PERFORMANCE CRITERIA**

The entire skill will be done in two to three minutes with 100% accuracy.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

- 1. Clear hands and forearms to wrist level.
- 2. Stand so that clothing does not touch the sink.
- 3. Turn on water. Adjust temperature to warm and leave the water running. Have paper towel or drying towel available.
- 4. Wet hands thoroughly with water, holding hands downward, lower than the level of the elbows throughout the procedure.
- 5. Apply soap or cleansing agent to hands using available products.
- 6. Wash hands using friction for sixty seconds:
  - a. Wash palms and back of hands using circular motions and friction for 10-15 seconds.
  - b. Rub the fingernails against the opposite hand to force soap under the nails for cleaning.
  - c. Wash between fingers by interlacing fingers and using friction for 10-15 seconds. If wedding band is in place, slide it up and wash beneath it.
- 7. Wash wrists and forearms using friction for 15 seconds.
- 8. Rinse hands and forearms well under running water with the fingertips downward.
- 9. Dry hands and forearms thoroughly with dry paper towel, from the fingertips upward. Do not contaminate the clean surfaces. Use a separate paper towel, or more as necessary, for each hand and forearm. Dispose of used paper towels in the waste container.
- 10. Turn off water with clean, dry paper towel held between the hand and faucet, without touching the sink. Dispose of the towel without touching the waste container.

The steps of performance have been numbered to show an appropriate sequence of completing the work; however, a different sequence may be used.



# **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Pass written tests of principles of hand washing technique observing medical asepsis.

## Demonstrate Procedure/Skill under Direct Observation:

Performance of procedure under supervision.



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# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Spill (real or simulated) of a chemical or biological hazardous material Paper towels

Absorbent material

OSHA-recommended personal protective equipment

Biohazard or contaminated waste container

# **WORK TO BE PERFORMED**

Decontaminate the surface disposing of all waste in the appropriate containers.

## PERFORMANCE CRITERIA

This skill standard requires 100% compliance throughout this exercise and in the course of demonstrating other laboratory skills.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

2. Identify the nature of the spill or contamination and select the appropriate absorbent and/or decontaminant and paper towels.

#### Perform Procedure:

3. Place absorbent material over contaminated surface. If a biological spill occurs, soak with disinfectant immediately. Continue to add absorbent material until the spill disappears.

#### Record, Evaluate and Report Results:

4. If the spill has resulted in an exposure, complete paperwork such as an incident report.

# Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

5. Dispose of waste into proper biohazard or contaminated waste container. Clean work area with disinfectant. Remove gloves and other personal protective equipment; discard into biohazard container. Wash hands with disinfectant.



# **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better differentiating contamination from disinfection and decontamination and matching the correct absorbent to the type of spill.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation describing the exposure, as applicable.

### Demonstrate Problem-Solving Skills:

Example: A tube of whole blood crashes to the floor. Describe the correct course of action.



5/0

## **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Typical day's waste to include blood, body fluids, sharps, contaminated microbiological materials and chemicals to include acids and bases OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Design and demonstrate a system (including containers) to segregate, handle, dispose of and/or recycle chemical, biohazardous and infectious wastes.

# **PERFORMANCE CRITERIA**

This skill standard requires 100% compliance throughout this exercise and in the course of demonstrating other laboratory skills.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

## Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment:

2. Collect an array of containers and bags to segregate, handle, dispose of and recycle the day's waste insuring that each container and each system complies with federal and state standards.

### Perform Procedure and Quality Control; Document and Evaluate:

- 3. Using this system, segregate, handle, dispose of and recycle the assembled waste products.
- 4. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

#### Record, Evaluate and Report Results:

5. Document any hazardous exposures.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to match the type of waste with the proper disposal system.



## Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation of any required logs and/or incidents of exposure.

### Demonstrate Problem-Solving Skills:

Example: Glass tubes containing human blood are found in a plastic biohazard bag. What is the recommended course of action?



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## **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

Given the following:

Fire or explosion

## **WORK TO BE PERFORMED**

Demonstrate rescue, alert, contain, extinguish and exit from the laboratory.

## PERFORMANCE CRITERIA

This skill standard requires 100% compliance throughout this procedure and in the course of demonstrating other skills.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Perform Procedure:

1. In the case of a fire or explosion, demonstrate the most likely rescue, alert, contain, extinguish and exit from any point as if in a darkened room.

#### Record, Evaluate and Report Results:

2. Document the drill, evaluate the simulation and make adjustment as may be needed.

# **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to identify rescue, alert, contain, extinguish and exit and techniques for exiting a burning room.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements within a given simulation.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.



### Complete Documentation of Log Sheets:

Competence is demonstrated through 95% compliance with complete documentation.

## Demonstrate Problem-Solving Skills:

Example: There is an exploding sound and the room is dark. Demonstrate the safest exit from the laboratory into safety.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Simulation of three different classes of fires Various fire extinguishers

## **WORK TO BE PERFORMED**

Demonstrate the use of the appropriate fire extinguisher.

## PERFORMANCE CRITERIA

This skill standard requires 100% compliance throughout this procedure and in the course of demonstrating other skills.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

## Assemble, Maintain and Monitor Equipment:

1. Collect the different types of fire extinguishers available in the laboratory. Note the last day of inspection and the last date of testing.

### Perform Procedure; Document and Evaluate:

2. Given a series of three different simulations and conditions, select and explain how to discharge each of the extinguishers.

#### Record and Evaluate Results:

3. Review results of the simulations and evaluate and debrief.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to identify the three classes of fires and match with the correct fire extinguisher type, contents and range; the three conditions required for a fire to exist; and steps to take in fire prevention.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.



Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation of the simulations and their evaluations.

### Demonstrate Problem-Solving Skills:

Example: An electrical fire breaks out on the incubator in microbiology. Only a Class B fire extinguisher is available. Describe the safest course of action.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Fire blanket Simulated exercise

## **WORK TO BE PERFORMED**

Demonstrate the use of a fire blanket.

## PERFORMANCE CRITERIA

This skill standard requires 100% compliance throughout this procedure and in the course of demonstrating other skills.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

## Assemble and Inspect Equipment:

1. Assemble and inspect the laboratory's fire blanket.

### Perform Procedure; Document and Evaluate:

2. Demonstrate the use of the fire blanket within the context of a simulation. Document and evaluate the exercise.

### Record, Evaluate and Report Results:

3. After reviewing the evaluation of the use of the fire blanket, debrief.

# **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test locating the fire blanket in the laboratory.

## Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation of the simulation, an evaluation of the event and a debriefing.

### Demonstrate Problem-Solving Skills:

Example: An explosion is heard. When the door to the exit is hot to the touch, how might the fire blanket be life saving in this situation?



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Laboratory data Calculator

## **WORK TO BE PERFORMED**

Report the values in metric units to the correct significant figure. This skill standard includes techniques to review data and reports and procedures for correcting reports and documenting the corrections.

# PERFORMANCE CRITERIA

The selection of values must include the reporting of enzymes, electrolytes, analytes such as glucose and therapeutic drugs, a variety of cell counts, reported per liter, microliter, picoliters, femtoliters to demonstrate a full range of samples that describe results expected in unknown specimens. Include a full range of reactivity from abnormal low, expected, to abnormal high ranges.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Assemble, Maintain and Monitor Equipment:

1. A calculator may be used in making conversions.

#### Document and Evaluate:

2. Report all data in the context of relevant age- and sex-related reference ranges including units.

### Record, Evaluate and Report Results:

3. Review all reports for clerical errors and for nonsense reports.

# **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to report laboratory results in metric units to the correct significant figure.

#### Demonstrate Procedure/Skill under Direct Observation:

: 1

Requires 100% compliance with performance elements and with zero clerical and/or reporting errors.



Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

### Demonstrate Problem-Solving Skills:

Example: The potassium level is reported as 56.7 mEq/L. Interpret this value and suggest a course of remediation to produce a corrected report.



## **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Range of pipettes

Receptacles for performing dilutions

Calculator

Relevant procedures

OSHA-recommended personal protective equipment

Biohazard container

# **WORK TO BE PERFORMED**

Demonstrate a set of five dilutions covering the range of uses from the following:

The concentration of the constituent being measured exceeds the linearity of the method used.

The less stable working solutions are prepared from standard or stock solutions.

It is necessary to express the potency or activity of cells of a constituent as in a serial dilution such as antibodies. There is no method of direct quantification of undesirable substances that interfere with testing which need to be diluted out.

# PERFORMANCE CRITERIA

A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens, including a full range of reactivity from abnormal low, expected, to abnormal high ranges.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment:

2. Assemble equipment to include a range of pipettes and receptacles to perform the dilutions, a calculator and relevant procedures.

### Perform Procedure and Quality Control; Document and Evaluate:

3. Repeat procedure as required after the dilution. Recalculate using the dilution factor.

### Record, Evaluate and Report Results:

4. Review result in the context of controls as a decision element in relationship to accepting and subsequent reporting of sample results.



# Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

5. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

# **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to define dilution, to describe the relationship of the concentration as indicated by dilution with the volume, to state how dilutions are expressed including the difference between a dilution and a ratio and a titer, and to identify situations in which dilutions are useful.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation

#### Demonstrate Problem-Solving Skills:

Example: On prenatal work-up, a mother demonstrates a Kell antibody. The physician must decide if an amniocentesis is indicated. The Transfusion Service elutes the antibody from the mother's cells and titers the strength of the potentially dangerous antibody. The laboratorian makes the following dilutions of the eluted antibody: 1:2; 1:4; 1:16; 1:32; 1:64; and 1:128. The antibody reacts with Kell positive cells through 1:32 dilution but not beyond. What is the reportable titer?



## TEST MANAGEMENT

## **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

### Given the following:

Authorized order for a laboratory test System for requesting the test

## **WORK TO BE PERFORMED**

## Complete the requisition to include the following information:

Demographic data (as applicable)

Name (or other unique identifier)

Age (if applicable)

Gender (if applicable)

Type of specimen

Name and address of person requesting the test (If the person who will utilize the test is different from the person ordering the test or different from person to be notified in the event the result indicates imminent lifethreatening danger, include the name and address of this individual also.)

Test /Procedures requested

Date and time of collection

Who collected the specimen

Additional information relevant and necessary to a specific test

Source of specimen

Presumptive diagnosis

Medications (if applicable)

# PERFORMANCE CRITERIA

The requisition is completed with zero clerical errors 100% of the time. The time to complete the task may vary according to completeness of information provided and the detail required.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

- Verify the authorized order. (Note: The laboratory must perform tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently obtains written authorization for testing within 30 days. Records of test requisitions or test authorizations must be retained for a minimum of two years. (CLIA '88 - 493.1105)\*
- 2. Refer to the laboratory manual for specimen collection or patient preparation requirements. Contact the laboratory if any questions arise.
- 3. Complete the requisition.



# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain why the required information may be important and valid reasons for specimen rejection.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. Demonstration of completing the requisition may be accomplished in a paper or an electronic, computerized form.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

### Demonstrate Problem-Solving Skills:

Example: The physician has ordered a xylose tolerance test. Design an algorithm for finding out how to complete a test requisition for this test.

Note: Illinois Clinical Laboratory Act states that except for waived tests only physicians are authorized to order tests. Each state must refer to its own local requirements.



## **TEST MANAGEMENT**

## **SKILL STANDARD**

# CONDITIONS OF PERFORMANCE

### Given the following:

Request for blood samples

Cooperative client

Syringe with needle

Label

Alcohol swab

Gauze

Tourniquet

Pressure bandage or Band-Aid

Blood tubes

OSHA-recommended personal protective equipment

Biohazard container

Sharps container

## **WORK TO BE PERFORMED**

Collect, label and transport a blood sample for routine analysis using a syringe as directed by authorized supervising personnel.

# PERFORMANCE CRITERIA

In routine circumstances, time to collect the blood sample in the correct tubes should not exceed eight minutes. Expected outcomes will be achieved 100% of the time. The sample is to be collected in an aseptic manner while protecting the client's rights.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### Client Preparation:

- 1. Proceed to client's location, knock and introduce self.
- 2. Explain procedure.
- 3. Identify client by comparing the facility-approved identification system with the requisition and/or prepared labels.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Include the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

4. Wash hands and put on gloves and other personal protective equipment.



#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

5. Assemble all needed equipment (syringe with needle, alcohol swab, gauze, tourniquet, pressure bandage or Band-Aid, required blood tubes and labels which include client name, location, date and time of collection, name of authorized person ordering the test, name of the person responsible for the collection and name of test(s) to be performed). Position equipment within easy reach.

#### Perform Venipuncture Procedure; Document and Evaluate:

- 6. Position client.
- 7. Attach the sterile, capped needle to the sterile syringe (if packed separately) maintaining sterility.
- 8. Slide the plunger up and down in the barrel of the syringe to ensure that the plunger moves freely.
- 9. Position the plunger at the bottom of the barrel so that no air remains in the syringe.
- 10. Place the tourniquet around the client's arm above the elbow. The tourniquet should be tight enough so that the venous circulation is restricted but not so tight that the arterial circulation is stopped. Do not allow the tourniquet to remain on for more than two minutes.
- 11. Instruct the client to close the fist to increase circulation and to make the veins more noticeable.
- 12. Inspect the antecubital fossa to locate a suitable vein.
- 13. Palpate the vein with the gloved fingertip to determine the direction of the vein and to estimate its size and depth.
- 14. Cleanse the skin of the puncture site using the alcohol prep.
- 15. Allow the alcohol to dry.
- 16. Uncap needle and hold the syringe with dominant hand so that the gradations on the syringe and the bevel of the needle are in full view. With thumb of other hand, hold skin taut.
- 17. Inspect the needle to see that the point is smooth and sharp.
- 18. Hold the needle at a 15-30 degree angle to the arm and insert the needle into the vein. Watch for blood to flow into the syringe.
- 19. Ask client to open the fist as soon as the vein has been entered and blood is returned.
- 20. Pull the plunger back slowly with the free hand to withdraw the blood while steadying the syringe and needle with the other hand.
- 21. Release the tourniquet when the desired amount of blood is obtained. Place dry gauze over the puncture site, withdraw needle and apply pressure.
- 22. Dispense blood into the correct sample tubes and attach completed label noting the time of collection.
- 23. Return to client and remove gauze from puncture site. If bleeding has stopped, apply a Band-Aid or pressure bandage. If the bleeding continues, apply pressure to the site until bleeding has completely stopped.

## Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 24. Dispose of all contaminated supplies in the biohazard containers and place needles in sharps containers.
- 25. Wash hands.
- 26. Thank the client for his/her cooperation.



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### Evaluate Sample/Specimen for Acceptability or Rejection:

27. Examine tubes to ensure that the correct specimens have been collected into the proper tubes. Invert all tubes. In samples collected in anticoagulated tubes, verify that specimen is not clotted. Inspect specimens to ensure adequate amounts were drawn and there is enough specimen to mix with the anticoagulants. Reject if inadequate and redraw.

#### Perform, Document and Evaluate Quality Control:

28. Evaluate each tube once again for hemolysis, inappropriate clotting, labeling, etc.

#### Record, Evaluate and Report Results:

29. Upon transporting specimens to the laboratory, record time of collection and time of arrival.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Tests of Principles:

Competence is demonstrated by a score of 90% or better on written tests to identify the names of common laboratory tests, the appropriate tube for collection, names of anticoagulants, the importance of timing of specimens, principle of standard precautions and infection control, and client's rights of refusal.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements to demonstrate the correct procedure for drawing blood sample with a syringe.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation by recording the time of collection and the time of the arrival of specimen into the laboratory. Review all requisitions, labels and logs for required information and evaluate the turnaround times.

#### Demonstrate Problem-Solving Skills:

Example: The following tests are required: a complete blood count, electrolytes and prothrombin time. In which order should the blood sample be dispensed into tubes?



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Request for blood specimens

Cooperative client

Adapter with needle

Alcohol swab

Gauze

Evacuated vacutainer tubes

Label

Blood tubes

Tourniquet

Pressure bandage or Band-Aid

Sharps container

OSHA-recommended personal protective equipment

Biohazard container

### **WORK TO BE PERFORMED**

Collect, label and transport a blood sample for routine analysis using evacuated vacutainer tubes and adapter as directed by authorized supervising personnel.

## PERFORMANCE CRITERIA

In routine circumstances, time to collect the blood sample in the correct tubes should not exceed eight minutes. Expected outcomes will be achieved 100% of the time. The sample will be taken in an aseptic manner while protecting the client's rights.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

- 1. Proceed to client's location, knock and introduce self.
- 2. Explain procedure.
- 3. Identify client by comparing the facility-approved identification system with the requisition or prepared labels.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

4. Wash hands and put on gloves and other personal protective equipment.



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#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

5. Assemble all needed equipment (adapter with needle; alcohol swab; gauze; tourniquet; pressure bandage or Band-Aid; required blood tubes; and labels which include client name, location, date and time of collection, name of authorized person ordering the test, name of the person responsible for the collection and name of test(s) to be performed). Position equipment within easy reach.

#### Perform Venipuncture:

- 6. Position client.
- 7. Attach the sterile, capped needle to the needle holder maintaining sterility.
- 8. Insert vacuum collection tube into needle holder but do not pierce stopper with needle.
- 9. Place other evacuated tubes within arm's reach if drawing more than one sample.
- 10. Place the tourniquet around the client's arm above the elbow. The tourniquet should be tight enough so that the venous circulation is restricted but not so tight that the arterial circulation is stopped. Do not allow the tourniquet to remain on for more than two minutes.
- 11. Instruct the client to close the fist to increase circulation and to make the veins more noticeable.
- 12. Inspect the antecubital fossa to locate a suitable vein.
- 13. Palpate the vein with the gloved fingertip to determine the direction of the vein and to estimate its size and depth.
- 14. Cleanse the skin of the puncture site using the alcohol prep.
- 15. Allow the alcohol to dry.
- 16. Uncap needle. Align vacutainer tubes in the order of draw and with the first tube inserted into the adapter. With thumb of other hand, hold skin taut.
- 17. Inspect the needle to see that the point is smooth and sharp.
- 18. Hold the needle at a 15-30 degree angle to the arm and insert the needle into the vein. Push the first tube onto the sample end of the needle within the adapter. Watch for the blood to flow into the tube.
- 19. Ask client to open the fist as soon as the vein has been entered and blood is returned.
- 20. When the first tube is full, remove it from the adapter and attach the next tube until the required blood is collected.
- 21. Release the tourniquet when the desired amount of blood is obtained. Place dry gauze over the puncture site, withdraw needle and apply pressure.
- 22. Attach completed labels to the tubes noting the time of collection.
- 23. Return to the client and remove gauze from puncture site. If bleeding has stopped, apply a Band-Aid or pressure bandage. If the bleeding continues, apply pressure to the site until bleeding has completely stopped.

## Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 24. Dispose of all contaminated supplies in the biohazard containers and place needles in sharps containers.
- 25. Wash hands.
- 26. Thank client for his/her cooperation.

### Evaluate Sample/Specimen for Acceptability or Rejection:

27. Examine tubes to ensure that the correct specimens have been collected into the proper tubes. Invert all tubes. In samples collected in anticoagulated tubes, verify that the specimen is not clotted. Inspect specimens to ensure adequate amounts were drawn and there is enough specimen to mix with the anticoagulants. Reject if inadequate and redraw.



#### Perform, Document and Evaluate Quality Control:

28. Evaluate each tube once again for hemolysis, inappropriate clotting, labeling, etc.

#### Record, Evaluate and Report Results:

29. Upon transporting specimens to the laboratory, record time of collection and time of arrival.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Tests of Principles:

Competence is demonstrated by a score of 90% or better on written tests to identify the names of common laboratory tests, the appropriate tube for collection, names of anticoagulants, the importance of timing of specimens, principle of standard precautions and infection control and client's rights of refusal.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements to demonstrate the correct procedure for drawing blood sample by vacutainer method.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation by recording the time of collection and the time of the arrival of specimen into the laboratory. Review all requisitions, labels and logs for required information and evaluate the turnaround times.

#### Demonstrate Problem-Solving Skills:

Example: The following tests are required: a complete blood count, electrolytes and prothrombin time. In which order should the blood sample be dispensed into tubes?



## SKILL STANDARD

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Request for blood specimens

Cooperative client

Lancet or other micropuncture device

Microtainer tubes

Alcohol swabs

Gauze

Filter paper or capillary tubes

Label

Sharps container

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Collect, label and transport a capillary blood sample for routine analysis using a lancet or other micropuncture device and microtainers as directed by authorized supervising personnel.

## PERFORMANCE CRITERIA

In routine circumstances, time to collect the blood sample in the correct microtainers should not exceed eight minutes. Expected outcomes will be achieved 100% of the time. The sample will be taken in an aseptic manner while protecting the client's rights.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

- 1. Proceed to client's location, knock and introduce self.
- 2. Explain procedure.
- 3. Identify client by comparing the facility-approved identification system with the requisition or prepared labels.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

4. Wash hands and put on gloves and other personal protective equipment.



#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

5. Assemble all needed equipment (lancet or other micropuncture device; alcohol swab; gauze; required microtainer tubes; filter paper or capillary tubes; and label which includes client identification, location, date and time of collection, name of the authorized person ordering the test, name of the person responsible for the collection and name of test(s) to be performed). Position equipment within easy reach.

#### Perform Capillary Puncture:

- Position patient and select and warm puncture site and/or let hand hang down.
- 7. Cleanse the puncture site with alcohol-soaked gauze or cotton.
- 8. Allow the site to air dry or wipe with dry, sterile gauze or cotton.
- 9. Position the puncture site to the side of the finger holding the skin taut with one hand and holding the lancet or other micropuncture device in the other hand and perpendicular to the skin.
- 10. Perform the capillary puncture using a quick, firm motion.
- 11. Wipe the first drop of blood away with sterile gauze or cotton.
- 12. Massage the puncture site gently to produce the second drop of blood.
- 13. If using a precalibrated capillary tube or microtainer tube, fill the capillary tube or other device to the line. If using an uncalibrated hematocrit tube, fill to two-thirds to three-quarters full.
- 14. Fill a second container in the same manner.
- 15. Either place the clean end of the capillary tubes into sealing clay or seal with plastic sealing caps as provided.
- 16. Apply pressure to the puncture site by pressing with dry sterile gauze or cotton. Instruct patient to continue applying pressure.
- 17. Place used puncture device into a puncture-proof sharps container. Discard used gauze or cotton into biohazard container.
- 18. Attach completed labels to tubes noting the time of collection.
- 19. Return to client and remove gauze from puncture site. If bleeding has stopped, apply a Band-Aid. If the bleeding continues, apply pressure to the site until bleeding has completely stopped.
- 20. Clean work area with surface disinfectant.
- 21. Remove and discard gloves into biohazard container. Wash hands with hand disinfectant.
- 22. Thank client for his/her cooperation.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

23. Examine tubes to ensure that the correct specimens have been collected into the proper tubes. In specimens collected in anticoagulated microtainers, verify that the specimens are not clotted.

#### Perform, Document and Evaluate Quality Control:

24. Evaluate each tube once again for hemolysis, inappropriate clotting, labeling, etc.

#### Record, Evaluate and Report Results:

25. Transport the specimens to the laboratory and record time of collection and time of arrival.



## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Tests of Principles:

Competence is demonstrated by a score of 90% or better on written tests to identify the names of common laboratory tests, the appropriate tube for collection, names of anticoagulants, the importance of timing of specimens, principle of standard precautions and infection control, and client's rights of refusal.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements to demonstrate the correct procedure for drawing blood sample using the capillary technique.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation by recording the time of collection and the time of the arrival of specimen into the laboratory. Review all requisitions, labels and logs for required information and evaluate the turnaround times.

#### Demonstrate Problem-Solving Skills:

Example: In collecting duplicate capillary tubes for a spun hematocrit test, an air bubble is spotted in one of the tubes. What is the next appropriate action?



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Cooperative client

Urine sample

Container with lid

Label

Bedpan, urinal or other collection device

Graduate pitcher

Completed laboratory requisition

OSHA-recommended personal protective equipment

Biohazard container

### **WORK TO BE PERFORMED**

Collect, label and transport a urine sample for routine urinalysis as directed by authorized supervising personnel.

### PERFORMANCE CRITERIA

Following collection of the urine sample, notify the authorized supervising personnel. In routine circumstances, time to collect the urine sample should not exceed ten minutes. Expected outcomes will be achieved 100% of the time. The sample will be taken in an aseptic manner while protecting the client's rights.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

 Assemble equipment (urine sample container with lid; label which includes client name, location, date and time of collection, physician's name, name of person responsible for the collection, name of test(s) to be performed; bedpan, urinal or other collection device; graduate pitcher if input/output measures are included in order; disposable gloves; completed laboratory requisition; and biohazard container for specimen transport).

#### Client Preparation:

- 2. Proceed to the client's room, knock, introduce self and identify the client by checking the facility approved identification system.
- 3. Explain the collection procedure to the client, family member or care giver. Provide for the client's privacy. Arrange appropriate screening.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

4. Wash hands and put on disposable gloves and other personal protective equipment.



#### Specimen Collection:

5. Instruct the client to void allowing the first urine to escape. Collect the continuous midstream portion into a paper cup or other collection device; pour a 10 - 15 mL aliquot into a plastic urine sample tube; or, as a last resort, instruct the client to void entire urine volume into a clean urinal, bedpan or other collection device that contains no other organic or biological material. If input/output measurements are ordered, measure and record entire volume. Mix well and pour 10 - 15 mL into a plastic urine sample tube. Instruct the client not to put toilet tissue into the urine collection device. Remove and clean any reusable equipment. Dispose of gloves.

## Evaluate Sample/Specimen for Acceptability or Rejection; Record, Evaluate and Report Results:

- 6. Apply the completed label to the specimen container, not to the lid of the container. Identify conditions and disposition of specimens that do not meet the laboratory's criteria for acceptability. For example, unlabeled specimens will be discarded. If specimen is unacceptable, proceed to recollect.
- 7. Return client to comfortable and safe position. Leave signal cord, telephone and fresh water close at hand. Return bed to lowest position. Remove screening used for privacy. Remove soiled linens. Wash hands.
- 8. Invite visitors to return to bedside.

#### Specimen Handling:

- 9. Transport the urine sample immediately to the laboratory in a portable cooler or other device designated for the transport of biohazardous materials.
- 10. If the urine sample cannot be transported immediately to the laboratory, cool the urine by placing in a cooler, surrounded by ice or a frozen ice gel block or in a refrigerator designated for biological specimens.
- 11. Report significant observations to authorized supervising personnel including observations about the condition of the client.

## Segregate, Handle, Recycle and Dispose of Chemical, Biohazardous and/or Infectious Waste:

12. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Tests of Principles:

Competence is demonstrated by a score of 90% or better on written tests of principles of physical care and observation for collecting a random urine specimen for routine urinalysis. Identify the specimen of choice for urine for routine urinalysis. For example, a continuous midstream, freshly voided, first morning, well-mixed urine is the most concentrated and is, therefore, the specimen of choice.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

. .

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.



Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

### Demonstrate Problem-Solving Skills:

Example: A random urine specimen for a routine urinalysis has been ordered. The client is bed bound. The bed pan for the collection of the sample had not been properly cleaned and dried. How might this situation influence the results of the routine urinalysis test? What costs may be involved?



### **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Cooperative client

Completed requisition

Urine container labeled with any required preservatives

System for keeping collected urine cool

Label

Sign for client's bed

Procedures for collecting a timed urine specimen in an aseptic manner, ensuring client rights are protected

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Collect an accurately timed urine specimen for quantitative analysis (such as a creatinine clearance or total protein). Write client height and weight on the laboratory slip.

### PERFORMANCE CRITERIA

During and following collection of the timed urine collection, notify the supervising personnel of any difficulty in completing the collection. An additional time limit is not appropriate for this skill standard. Expected outcomes will be achieved 100% of the time. Coordinate collection with the laboratory personnel to ensure the proper preservative, if required, is added to the urine collection system and to ensure that accurately timed corresponding blood specimens are collected.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

1. Assemble equipment (an adequate urine container labeled with any required preservatives for collecting urine, a system with biohazard labels for keeping collected urine cool such as a styrofoam container with frozen gel bricks or ice, label, sign for client's bed indicating procedure is in progress and disposable gloves).

#### **Patient Preparation:**

2. Go to client's room, knock, introduce self and identify the client by checking the facility-approved identification system. Explain the procedure to the client, family member or care giver. Emphasize to the client the necessity of saving all urine passed during the collection period. Provide for the client's privacy arranging appropriate screening. When a blood specimen is required as part of the procedure, as in the case of the creatinine clearance, advise the client that blood work will be drawn.



- 3. Label the container with the client's name, identification number as required, location, date, ordering physician's name, tests ordered, type of specimen, name of person responsible for the collection, time collection started and time collection ended.
- 4. Place a sign on the client's bed noting the beginning of the timed urine collection. A sign noting the collection period may also be placed in the bathroom as a client reminder.
- 5. Wash hands.
- 6. Put on disposable gloves.
- 7. Request the client to void assisting as needed. If output is monitored, measure and record the amount of urine passed; discard this specimen and note the time of voiding. The Timing for Collection Begins Now.
- 8. Take off gloves and wash hands.

#### Specimen Collection and Handling:

- 9. Putting on gloves for each event, collect all urine and add to cooled specimen container for the designated time interval. Take off gloves and wash hands.
- 10. At the end of the collection period, put on gloves and ask the client to void one last time adding this urine to the container. Note the time of this last voiding.
- 11. Remove, clean and/or dispose of equipment used for collecting the timed urine specimen. Store reusable items. Remove gloves and wash hands.
- 12. Restore the client to comfortable and safe position leaving the bed in the lowest position; leave signal cord, telephone and fresh water close at hand; remove any privacy screening and remove soiled linens. Wash hands.
- 13. Thank client for his/her cooperation. Remove sign from client's bed. Check container label for accuracy and completeness. Attach the appropriate laboratory requisition with any observations regarding the condition of the client and accuracy and completeness of the timed urine collection. Arrange for immediate transport of the urine specimen to the laboratory.
- 14. Invite visitors to return to bedside.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Written Test of Principles:

Written tests of principles to describe physical care and observation for collecting a timed (24, 12, 6, 4, 2 hour) urine specimen.

#### Demonstration of Procedure/Skill under Direct Observation:

Demonstration of collection procedure for selected client including recording times and volumes.

## Identify Conditions and Disposition of Specimens That Do Not Meet the Laboratory's Criteria for Acceptability:

For example, unlabeled specimens will be discarded.

#### Demonstrate Problem-Solving Skills:

Example: During the timed urine collection, the client becomes nauseated and vomits. At the same time the client voids and fails to save this specimen. How is the timed urine collection affected? Explain and suggest how to proceed.



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Cooperative client

Sterile urine specimen container

Container label

Gauze squares or cotton

Antiseptic solution

Clean catch kit

Supervision of authorized personnel

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Collect, label, store and transport a urine specimen for culture and sensitivity.

### PERFORMANCE CRITERIA

Following collection of the urine specimen, notify the authorized supervising personnel of any difficulty in completing the collection. Time to collect a clean catch urine for culture and sensitivity will vary according to the client condition but should not exceed ten minutes excluding the time for documentation. Skill will be performed with 100% accuracy. The collection will be completed in a safe manner while protecting the client's rights.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Assemble equipment as needed (sterile urine specimen container; disposable
gloves; container label which includes client's full name, room number, date
and time of collection, ordering physician's name, type of specimen and test(s)
to be performed; gauze squares or cotton; antiseptic solution; biohazard bag;
or a clean catch kit). Note: The urine specimen obtained through clean catch
procedures is preferable to the specimen obtained through
catheterization because of the danger of introducing bacteria via the second
procedure.

#### Patient Preparation:

2. Go to the client's room, knock, introduce self and identify the client by checking the arm bracelet or using facility-approved and accepted method of identification. Explain the procedure to the client, family member or care giver. Early morning specimens yield highest bacterial counts from the overnight incubation of the urine in the bladder. A urine specimen should be collected prior to beginning antibiotic therapy. In the event that antibiotics have been started or just completed, list these antibiotics on the laboratory request form. Arrange for privacy of the client.



- 3. Wash hands.
- 4. Put on disposable gloves and other personal protective equipment.

#### Specimen Collection:

#### 5. FEMALES

- a. Remove patient's underclothing and have her sit comfortably on the toilet seat, swinging one knee to the side as far as possible.
- b. Using a forward to back motion, cleanse the periurethral area and the perineum with two to three gauze pads saturated with soap as provided with the clean catch kit. Rinse with sterile saline or water.
- c. During the voiding, hold the labia apart.
- d. Allow the first few milliliters of urine to pass into the toilet or bed pan to flush out bacteria from the urethra.
- e. Collect the midstream portion of urine in a sterile, wide-mouthed container that can be covered with a tightly fitted lid.

#### 6. MALES

- a. Expose the penis.
- b. Cleanse the urethral meatus immediately before voiding.
- c. Allow the first few milliliters of urine to pass into the toilet or bed pan to flush out bacteria from the urethra.
- d. Collect the midstream portion of urine in a sterile, wide-mouth container that can be covered with a tightly fitted lid.
- 7. Remove the materials used in collecting the clean catch urine specimen. Dispose of items according to facility protocol. Cleanse any reusable items prior to storage. Remove and dispose of gloves according to facility policy. Wash hands. If client has been responsible for cleansing and collecting the specimen, provide hand washing materials to the client.
- 8. Restore client to comfortable and safe position. Leave signal cord, telephone and fresh water at arm's reach; return bed to lowest position; remove screening used for privacy; and remove soiled linens. Wash hands.
- 9. Invite visitors to return to bedside.
- Report observations to supervising personnel to include the condition of the client, degree of strength during the procedure and tolerance of the activity.

#### Specimen Handling:

- 11. Attach a completed label to the capped, sterile urine container.
- 12. Place the container in the cooler for immediate transport to the laboratory within 30 minutes of collection.
- 13. If the urine cannot be brought to the laboratory immediately, place a frozen gel coolant around the specimen. Do not store the urine specimen in a refrigerator along with food or medication. Store specimens only in units that are designated specifically to hold biological specimens.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Pass a written test of principle of physical care and observation in collecting a clean catch urine specimen for culture and sensitivity.

#### Demonstrate Procedure/Skill under Direct Observation:

Perform collection procedure for selected client.



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## Identify Conditions and the Disposition of Specimens That Do Not Meet the Laboratory's Criteria for Acceptability:

- 1. Unlabeled specimens will be discarded.
- 2. Specimens that have set at room temperature longer than 30 minutes without refrigeration will be rejected.
- 3. Specimens arriving in unsterile containers will be discarded.
- 4. Specimens should be plated within 24 hours unless placed in a preservative.

### Demonstrate Problem-Solving Skills:

Example: A cloudy, refrigerated urine sample for culture and sensitivity arrived in the laboratory 12 hours after collection. The specimen is properly labeled. What is the appropriate disposition of this specimen?



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Cooperative client

Sterile specimen container

Water

Emesis basin

Tissue

Label

OSHA-recommended personal protective equipment

Biohazard bag or container

## **WORK TO BE PERFORMED**

Collect, label and transport a sputum specimen.

### PERFORMANCE CRITERIA

Following collection of the sputum specimen, notify authorized supervising personnel of any difficulty in completing the collection. Time will vary according to client condition; however, sputum collection should not exceed ten minutes. Skill shall be performed with 100% accuracy and in a safe manner while protecting the client's rights.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

 Assemble equipment (sterile specimen container; water for gargling; emesis basin; tissue to cover client's mouth during coughing; label including client's name, location, ordering physician, date and time of collection, test(s) ordered, type of specimen and name of person responsible for the collection; antibiotic therapy, if any; and disposable gloves).

#### Patient Preparation:

- 2. Go to client's room, knock, introduce self and identify the client by checking the facility-approved identification system. Explain the procedure to the client, family member or care giver. An early morning sputum sample contains pooled overnight secretions and is the specimen of choice. Provide for privacy of the client.
- 3. Wash hands.
- 4. Put on disposable gloves and other personal protective equipment.
- 5. Ask the client to gargle with water to reduce the number of contaminating oropharyngeal bacteria. Use emesis basin for waste.



#### Specimen Collection:

6. Ask client to take a deep breath, cough deeply to bring up sputum and expectorate into the labeled container. Have client cover mouth with tissue during deep coughing to prevent the spread of infection. Collect 1-2 table-spoonsful of sputum into the labeled container unless otherwise ordered. Do not touch the inside of the container. Put lid onto the container immediately.

#### Specimen Handling:

- 7. Decontaminate any non-disposable equipment used in the collection of the sputum specimen. Dispose of unrecyclable wastes, including gloves, and wash hands.
- 8. Restore the client to a comfortable and safe position. Leave signal cord, telephone and fresh water close at hand; return bed to lowest position; remove screening used for privacy; remove soiled linens and wash hands.
- 9. Invite visitors to return to bedside.
- Report and record completion of sputum collection to authorized supervising personnel. Include any observations about client condition or about sputum collected.
- 11. Transport the sputum specimen in a biohazard bag or container to the laboratory.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Tests of Principles:

Pass written tests of principles of physical care and observation for collecting sputum specimens.

#### Demonstrate Procedure/Skill under Direct Observation:

Perform collection procedure for selected client.

## Identify Conditions and Disposition of Specimens That Do Not Meet the Laboratory's Criteria for Acceptability:

For example, unlabeled specimens will be discarded.

#### Demonstrate Problem-Solving Skills:

Example: Upon receiving the sputum sample, the laboratory personnel performed a Gram's stain to screen for contamination with oropharyngeal epithelial and white blood cells. Only organisms commonly found in saliva were identified. What will be the disposition of this specimen?



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Cooperative client

Bedpan and cover or diaper

Specimen container

Tongue blades and/or commercially prepared collection system

Label

OSHA-recommended personal protective equipment

Completed laboratory requisition

Biohazard container

## **WORK TO BE PERFORMED**

Collect, label and transport a stool sample as directed by authorized supervising personnel.

### PERFORMANCE CRITERIA

Following collection of the fecal sample, notify authorized supervising personnel of any difficulty or unusual observation encountered in obtaining the specimen. Time to collect the stool specimen will vary according to client condition but should not exceed ten minutes. Skill will be performed with 100% accuracy and in a safe manner while providing privacy and protecting the client's rights.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

- Assemble equipment (bedpan and cover; specimen container; tongue blades and/or commercially prepared collection system; label to include client name, location, date and time of collection, ordering physician's name, name of person responsible for the collection, name of test(s) such as ova and parasites, culture and sensitivity to be performed; disposable gloves; completed laboratory requisition; biohazard container for specimen transport).
- 2. Proceed to client's room, knock, introduce self and identify the client by comparing the facility-approved identification system with the requisition.
- 3. Explain the collection procedure to the client, family member or care giver. Provide for the client's privacy. Arrange appropriate screening.
- 4. Wash hands.
- 5. Put on disposable gloves and other personal protective equipment.
- 6. Ask the client to defecate into a clean, dry bedpan or diaper. Do not contaminate the specimen with urine or toilet tissue.



- 7. Use tongue blades or the collection spoon built into the lids of the commercially prepared kit to remove a representative specimen from the bedpan or other collection device. If a portion of the specimen is bloody, purulent, slimy or watery appearing, select the sample from this material. Place the selected sample into the specimen container(s) without contaminating the outside of the container. When the collection requires preservative, mix the contents of the tube with the specimen, cap the container and shake vigorously.
- 8. Attach the completed label(s).
- 9. Place the specimen(s) in a plastic bag for the transport of biohazardous materials. Transport to the laboratory immediately.
- 10. Remove and clean reusable equipment soiled in collecting the fecal specimen.
- 11. Wash hands thoroughly after degloving.
- 12. Restore client to comfortable and safe position. Leave signal cord, telephone and fresh water close at hand; return the bed to lowest, safe position; remove screening used for privacy; remove soiled linen; and wash hands.
- 13. Invite visitors to return to bedside.
- 14. Report completion of the fecal specimen collection to the authorized supervising personnel. Include any observation about the condition of the client and/or the stool specimen.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Tests of Principles:

Pass written tests of principles of physical care and observation for collecting stool specimens.

#### Demonstrate Procedure/Skill under Direct Observation:

Perform procedure for selected client.

## Identify Conditions and Disposition of Specimens That Do Not Meet the Laboratory's Criteria for Acceptability:

For example, all unlabeled specimens will be discarded.

#### Demonstrate Problem-Solving Skills:

Example: The client is thought to have *shigella* food poisoning. How is this infection transmitted and how must health care personnel protect their own health and safety in collecting and transporting this fecal sample?



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Order to culture a purulent wound site

Suspected diagnosis

Cooperative client

Sterile swabs or aspirate

Dressing

Three pairs of gloves

OSHA-recommended personal protective equipment

Portable cooler

Biohazard container

## **WORK TO BE PERFORMED**

Collect, label and transport a specimen (two swabs) from wound drainage and redress the wound as required.

### PERFORMANCE CRITERIA

Following collection, notify authorized supervising personnel of any difficulty or unusual observation encountered in obtaining the specimen. The time to perform the collection will vary according to client condition but should not exceed twenty minutes. Skill must be performed with 100% accuracy and in a safe and aseptic manner while protecting the client's rights.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Assemble Supplies:

1. Assemble supplies to include materials to clean the wound, a minimum of two sterile swabs, dressing to rebandage the wound and a minimum of three pairs of gloves.

#### Client Preparation:

- 2. Proceed to the client's room, knock, introduce self and identify the client by checking the facility-approved identification system.
- 3. Explain the collection procedure to the client, family member or care giver. Provide for the client's privacy. Arrange appropriate screening.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

4. Wash hands and put on disposable gloves and other personal protective equipment.



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#### Evaluate Sample/Specimen for Acceptability or Rejection:

5. The most meaningful specimens are collected in the acute phase of the infection before antibiotics are administered. If an antibiotic has been administered for any reason and if 48 to 72 hours has not elapsed, record the antibiotic on the label or otherwise inform the laboratory.

### Perform Procedure and Quality Control; Document and Evaluate:

- 6. Select the purulent section of the wound, avoiding the usual flora and colonizing organisms.
- 7. Clean the Wound to remove endogenous flora and contaminants and to present the organisms responsible for the infection. Change gloves.
- 8. Explore the Wound to determine the deepest part of the opening.
- 9. Obtain Fresh Culture Material. Avoid pus from draining lines, bags or old drainage. Remove the swab from its protective sheath.
- 10. Obtain an Adequate Quantity of Material. Once the swab of the wound has been obtained, return the swab to its sheath and activate the preservative. Repeat, using the second swab. (Because gram stains are performed on wound for culture and sensitivity, a minimum of two swabs is required.)
- 11. Dispose of gloves, wash hands and put on clean gloves and redress the wound as required by facility protocol.

## Evaluate Sample/Specimen for Acceptability or Rejection; Record, Evaluate and Report Results:

- 12. Apply the completed label to the swab containers. Include date and time of collection. Identify conditions and disposition of specimens that do not meet the laboratory's criteria for acceptability. For example, unlabeled specimens will be discarded. If specimen is unacceptable, proceed to recollect.
- 13. Return client to comfortable and safe position. Leave signal cord, telephone and fresh water close at hand; return bed to lowest position; remove screening used for privacy; remove soiled linens; and wash hands.
- 14. Invite visitors to return to bedside.

#### Specimen Handling:

15. Transport the swabs immediately to the laboratory in a portable cooler or other device designated for the transport of biohazardous materials.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

16. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to describe the basic principles of collecting a specimen from a wound culture and sensitivity and methods of maintaining organism viability relating to preservation, storage and transport of specimens.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.



Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The client has an open wound, even after ten days of topical antibiotic. The last application of antibiotic was 0700. Swabs for culture and sensitivity were taken and sent to the laboratory at 1200 hours. What is the recommended course of action?



## SKILL STANDARD

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Order to collect a specimen for pinworm by cellophane tape or paddle

Cooperative client

Cellophane tape preparation or paddle

OSHA-recommended personal protective equipment

Completed label

## **WORK TO BE PERFORMED**

Collect, label and transport a cellophane tape or paddle preparation.

## PERFORMANCE CRITERIA

Following collection, notify authorized supervising personnel of any difficulty or unusual observation encountered in obtaining the specimen. The time to perform the collection will vary according to client condition but should not exceed five minutes. Skill must be performed with 100% accuracy.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Assemble Supplies:

1. Assemble supplies to include a cellophane tape preparation or a paddle and gloves.

#### Client Preparation:

- 2. Proceed to the client's room, knock, introduce self and identify the client by checking the facility-approved identification system.
- 3. Explain the collection procedure to the client, family member or care giver. Provide for the client's privacy. Arrange appropriate screening.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

4. Wash hands and put on disposable gloves and other personal protective equipment.

#### Perform Procedure; Document and Evaluate:

- 5. The life cycle of the pinworm includes migration of the female out of the anus at night to lay eggs in the perianal area. The specimen of choice is taken first thing in the morning, before the client uses the bathroom or bathes.
- 6. Remove underclothing and swab the perianal area with a tongue blade covered with cellophane tape (sticky side out) or the paddle.



## Evaluate Sample/Specimen for Acceptability or Rejection; Record, Evaluate and Report Results:

- 7. Apply the completed label to the specimen. Include date and time of collection. Identify conditions and disposition of specimens that do not meet the laboratory's criteria for acceptability. For example, unlabeled specimens will be discarded. If specimen is unacceptable, proceed to recollect.
- 8. Return client to comfortable and safe position. Leave signal cord, telephone and fresh water close at hand; return bed to lowest position; remove screening used for privacy; remove soiled linens; and wash hands.
- 9. Invite visitors to return to bedside.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

10. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written examination to explain the life cycle of *Enterobius vermicularis* and to explain why a fecal specimen is not optimal for detection of infection with this organism.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A fecal specimen arrives in the laboratory with a request to scan for pinworm. What is the best course of action?



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## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Order to culture a throat to detect pathogens

Suspected diagnosis

Cooperative client

Two sterile culturettes

Tongue blade

Flashlight

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Collect, label and transport a specimen (two swabs) from the throat in a safe and aseptic manner while protecting the client's rights. On the laboratory request form, confirm that antibiotics have not been started prior to the culture; or if antibiotics have been taken, identify the antibiotics.

### **PERFORMANCE CRITERIA**

Following collection, notify authorized supervising personnel of any difficulty or unusual observation encountered in obtaining the specimen. For example, any film over the throat area must be reported immediately to the physician and to the laboratory. The time to perform the collection will vary according to client condition and cooperation, but should not exceed ten minutes. Skill must be performed with 100% accuracy.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

- 1. If the client is taking antibiotics for the sore throat or for some other ailment, note the antibiotic on the laboratory request form.
- 2. Explain the procedure to the client. Explain that he/she may gag during the swabbing. Explain that the procedure may take up to one minute. If applicable, remove dentures.
- 3. Instruct the client to sit erect on the edge of a chair or bed, if possible. If in a bed, position the resident in a supine position with head tilted back.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

4. Wash hands and put on disposable gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

5. Assemble two culturettes, tongue blades and a flashlight.



#### Perform Procedure and Quality Control, Document and Evaluate:

- 6. Peel the paper wrapper from the culturettes.
- 7. Ask the client to breathe deeply and gently depress the tongue with the tongue blade. Illuminate the throat with the flashlight.
- 8. Pull the swab from the protective sheath and extend the swab between the tonsillar pillars and behind the uvula. Sweep the swab back and forth across the posterior pharynx, including any inflamed or purulent sites. If there are any white films across the throat, do not penetrate with the swab. Do not touch the lateral wall of the buccal cavity, the tongue or teeth with the swab.
- 9. Return the swab to the protective sheath. Activate the transport media by crushing the central part of the tube.
- 10. Proceed with the second swab.
- 11. Complete the labels on the transport tubes with the client's name, sex, identification number, date of birth and time and date of collection. If the suspected organism is any of the following, alert the laboratory so that special media may be ordered.
  - a. Corynebacterium diphtheriae
  - b. Bordetella pertussis
  - c. Neisseria gonorrhaoeae
  - d. Borelia vincentii
- 12. Record the time, date and site of specimen collection and any unusual appearance of the throat specimen.
- 13. Transport immediately to the laboratory. Unlabeled specimens will be discarded. The laboratory will reject any culture that exceeds the time preservation limits of the transport media.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

14. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Tests of Principles:

Competence is demonstrated by a score of 90% or better to describe the basic principles of collecting a specimen from a throat and methods of maintaining organism viability relating to preservation, storage and transport of specimens. Include the criteria for reporting the presence of Group A Streptococcus to the appropriate state departments of public health.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The throat culture arrives in the laboratory 72 hours post collection. Describe a course of action.



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**BODY FLUIDS** 

## SKILL STANDARD

### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Properly labeled and adequate urine sample

Completed requisition

Controls

Written procedure

Accession log sheet

Reporting system

Procedure

Equipment

Reagents

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Note and record the time of urine collection. If time of collection has been more than one hour, note how sample was stored. Examine and record physical characteristics to include appearance/clarity and color.

## PERFORMANCE CRITERIA

Skill requires one minute per sample. Qualitative determination may vary slightly. Recording standard is 100% accuracy.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Assemble Supplies:

1. Assemble equipment, reagents, controls and log sheets.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands; put on disposable gloves and other personal protective equipment.

Identify Conditions and Dispositions of Specimens That Do Not Meet the Laboratory's Criteria for Acceptability:

3. Evaluate sample against standards of specimen rejection.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 4. Mix urine. Observe and record the appearance of urine and controls. Record as clear, hazy, slightly cloudy or cloudy. In the occasional situation when the urine presents a sweet, fruity or other unusual odor, record this observation.
- 5. Observe and record the color of urine. Record as colorless, pale yellow, yellow, amber, white, pink, red, brown, purple, black, blue or green.



#### Record, Evaluate and Report Results:

- 6. Review the sample results. If results appear valid, record and report results.
- 7. Initial and date report.
- 8. Proceed to chemical examination or dispose of urine.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written examination to list and to explain the implications of the physical characteristics of urine to include color, clarity, colligative property, foam and odor.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate procedure under direct observation to include testing process and accurate recording and reporting of results. Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

Examine a proficiency sample, blind or split sample or other previously analyzed specimen and match results to recorded or published standard.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A patient is asked to provide a urine specimen in a physician's office. The specimen is clear and colorless. What are some possible explanations?



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**BODY FLUIDS** 

### **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Urine sample

Dry reagent test strip for urine chemistries

Timer

Controls

Written procedure

Log sheet

Reporting system

Unknowns

Test tubes

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Given a minimum of five unknown samples, representing the full range of possible results, test urine and record results for any combination of the following: specific gravity, pH, leukocytes, nitrite, protein, glucose, ketone, urobilinogen, bilirubin, blood and/or hemoglobin. Verify that reagents have been stored in dry area and out of direct light. Specific gravity may be determined alternatively by reagent strip or by refractometer.

## PERFORMANCE CRITERIA

Skill requires a minimum of two minutes and a maximum of three minutes per sample to perform, read and record. Quantitative determinations such as specific gravity require results to be  $\pm 2$  SD or 0.010 of target values whichever is greater. Qualitative determinations may vary slightly from individual to individual. Recording standard requires 100% accuracy.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Assemble Equipment, Reagents and Controls:

1. Assemble and label controls and test tubes to match work log.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands; put on disposable gloves and other personal protective equipment.

Identify Conditions and Dispositions of Specimens That Do Not Meet the Laboratory's Criteria for Acceptability:

3. Evaluate sample against standards for specimen rejection.



#### Perform Procedure and Quality Control: Document and Evaluate:

- 4. Mix first the controls and then the urine sample individually and in succession; briefly (no longer than one second) dip one test strip into each sample.
- 5. Draw the edge of the strip along the rim of the specimen container to remove excess sample.
- 6. Turn the test strip on its side and tap once on a piece of absorbent paper to remove any remaining sample and to prevent any possible mixing of chemicals. Start timer.
- 7. If a refractometer and/or automated dipstick reader is used, perform and record routine instrument maintenance, calibrations and performance checks. Refractometer must be zeroed with water.
- 8. Following the procedure specified by the particular dry reagent chemistry manufacturer and after the designated time for each test, orient the test strip to match the color chart on the vial label. If colors are the same for two levels, report the lower level.
- 9. If the glucose, protein, ketone or bilirubin are positive, test to confirm following the laboratory's protocols and procedures.

#### Record, Evaluate and Report Results:

10. Evaluate results and control values in relation to published confidence limits and accept or reject.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

11. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Tests of Principles:

Pass a written test by a score of 90% or better on chemical principles behind each test and descriptions of potential risks for false positives or false negatives for each test. Describe related pathologies.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the procedure under direct observation to include testing process and accurate recording and reporting of test results. Competency requires 100% compliance with performance elements. If specific gravity is determined with a refractometer or other device, compliance includes a function check of the instrument.

Demonstrate Successful Performance with a Proficiency Sample, Blind or Split Sample or Other Previously Analyzed Specimen, Matching Results to Recorded or Published Standards:

Test a proficiency sample, a blind or split sample or other previously analyzed specimen and match results to recorded or published standard.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A client reports ingesting 1000 mg of ascorbic acid daily for the past three weeks in an effort to avert a cold. What effects might ascorbic acid have on urine chemistry results?



**BODY FLUIDS** 

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Urine sample

Centrifuge

Microscope

Controls

Written procedure

Log sheet

Reporting system

Slides

OSHA-recommended personal protective equipment

### **WORK TO BE PERFORMED**

Examine and record observations of a urine sediment for the following elements: erythrocytes, leukocytes, epithelial cells, crystals, casts, bacteria, yeast, sperm, mucous, amorphous urates, talc or other artifacts and parasites. A sediment stain may or may not be a part of this performance skill standard.

### **PERFORMANCE CRITERIA**

Skill varies based on the health or pathology of the sediment. Sediment displaying no formed elements may be discarded in under a minute. Urine sediment with a variety of formed elements may require up to three minutes to evaluate.

Qualitative descriptors may vary slightly from individual to individual. Recording standard requires 100% accuracy.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Assemble Equipment, Reagents and Controls:

1. Assemble and label controls and slides to match work log.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on disposable gloves and other personal protective equipment.

Identify Conditions and Dispositions of Specimens That Do Not Meet the Laboratory's Criteria for Acceptability:

3. Evaluate sample against laboratory's standards for specimen rejection.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 4. Mix 10-15 mL of controls and of the specimen. Place in a balanced centrifuge. Spin at 400 to 450 g (relative centrifugal force) for 5 minutes.
- 5. Using some quantifiable system, pour off all but one milliliter of supernatant fluid. Resuspend urine sediment in residual liquid. Mix the sediment. (The lab may or may not add a supervital stain to the sediment at this point.)
- 6. Place a drop of sediment into a calibrated chamber or onto a glass slide. (If using the glass slide, apply a cover slip and examine under the microscope immediately.)
- 7. Demonstrate the use of subdued light and continuous fine adjustment to differing focal planes. Review under 10 x and 40 x for formed elements in the urine. Examine 10-15 high power fields per sample looking for epithelial cells or casts.

#### Record, Evaluate and Report Results:

8. Evaluate controls and/or split samples as a decision element in relationship to accepting and subsequent reporting of sample results.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

9. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Tests of Principles:

Written tests of origin of various formed elements and related pathology and identification of photomicrographs of the various formed elements.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstration under direct observation to include sediment preparation, scope adjustments, reading of the microscopic sediment and quality control material and accurate recording and reporting of test results.

Demonstrate Successful Performance with a Proficiency Sample, Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Test a proficiency sample, a blind or split sample or other previously analyzed sediment. Match results to recorded or published standard.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs, Proficiency Testing: Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Differentiate yeast cells from red blood cells.



**BODY FLUIDS** 

## SKILL STANDARD

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Cerebrospinal fluid or a credible simulation

**Procedures** 

OSHA-recommended personal protective equipment

Hemocytometer

Slides

Stains

Culture methods

Equipment for protein, glucose and lactate analysis

Biohazard container

### **WORK TO BE PERFORMED**

Describe the physical characteristics to include clarity, color and viscosity; the microscopic characteristics to include number and types of cells; and/or other formed elements, if present. Perform the chemical examinations as requested, to include protein, glucose and lactate. Prepare for IgG, albumin or myelin-basic protein. Send to culture. Stain for the presence of microorganisms and/or specific immunologic examinations.

## PERFORMANCE CRITERIA

Evaluate a minimum of five challenge samples or simulated materials that demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity from abnormal low, expected to abnormal high ranges. The evaluation of a cerebrospinal fluid may take one or more hours depending on the pathology of the sample.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

2. Assemble supplies to include hemocytometer, slides, stains, culture methods and equipment for protein, glucose and lactate analysis as requested.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

3. In particular, gross blood in cerebrospinal fluid requires differentiation between a traumatic puncture and a subarachnoid or intracerebral hemorrhage.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 4. Perform physical examination describing clarity, color and viscosity. Split sample as required. Take first aliquot to microbiology for culture.
- 5. Perform microscopic examination. Differentiate the cell population, if present.
- 6. Proceed to chemical examination performing at least a total protein and glucose. Proceed to lactate, albumin, IgG, myelin-basic protein and protein electrophoresis as required.
- 7. Perform gram stain for microorganisms. Proceed to immunologic evaluation as required.

#### Record, Evaluate and Report Results:

8. Includes the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

9. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to describe the formation and functions of cerebrospinal fluid, the significance of timely processing and analysis to compare normal characteristics with observations in disease states and the clinical relevance of each.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards. This may be demonstrated through proficiency testing.

# Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A labeled specimen arrives in the laboratory. However, the origin of the sample is in question. Other than asking personnel who might have collected the specimen, how can one positively identify the sample as cerebrospinal fluid?



**BODY FLUIDS** 

### **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Fecal specimen

Commercially prepared slides or labeled containers

Applicator sticks

Timer

Biohazard container

Hydrogen peroxide developer

Reagents

OSHA-recommended personal protective equipment

### **WORK TO BE PERFORMED**

Collect a fecal (stool) specimen or use a specimen collected by a physician during a rectal examination or sigmoidoscopy or by the patient at home obtaining three specimens on three consecutive stools. Apply fecal sample to the commercially prepared hemocult slide and test within two days.

## PERFORMANCE CRITERIA

Skill requires eight minutes per sample with 100% accuracy.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### **Patient Preparation:**

1. Instruct the patient regarding dietary and drug restrictions (three days of diet to restrict red meat [beef or lamb], horseradish, beets or fresh fruits or vegetables exhibiting peroxidase activity). Provide either three labeled, commercially prepared slides or other labeled containers for three stool collections on three consecutive stool specimens. Provide applicator sticks. In addition, review for the patient the instructions on the slide and ask if he/she has any questions.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

2. Assemble applicator sticks and slides (if not already prepared), gloves, disinfectant, timer, biohazard container and hydrogen peroxide developer.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

 Wash hands and put on disposable gloves and other personal protective equipment.



### Evaluate Sample/Specimen for Acceptability or Rejection:

4. If sample is fresh, wait three to six minutes before developing. Otherwise, fecal smeared slides may be stored up to 14 days until ready to develop.

#### Perform Procedure:

- 5. If specimen is available but not applied to slides, fill out the patient information on the front of the slide package.
- 6. Open the flap on the front to expose the two paper guaiac squares. Follow the directions and obtain a small portion of the stool sample on the applicator stick. Apply a thin smear to the first box.
- 7. Reuse the applicator stick to obtain a second sample from a different part of the stool. Apply a thin smear to box B.
- 8. Close the cover and wait three to five minutes for the smears to dry.
- 9. Turn slide over and open the perforated flap to expose the backs of the two boxes and the performance monitor that serves as  $a \pm control$ .
- 10. Apply two drops of developer onto each of the fecal smears.
- 11. Read the results in 60 seconds.
- 12. Any blue color is a positive test.

### Perform, Document and Evaluate Quality Control:

13. Apply one drop of developer between the positive and negative performance monitor areas. Read these results in ten seconds. If the performance monitors do not work, the test must be repeated using a new slide.

### Record, Evaluate and Report Results:

- 14. Record results of the test and the controls.
- 15. Dispose of all potentially infectious materials in a biohazard container.
- 16. Wipe the counter with surface disinfectant.
- 17. Return equipment and reagents to proper storage.
- 18. Remove gloves and discard into biohazard container.
- 19. Wash hands with disinfectant.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Tests of Principles:

Competence is demonstrated by a score of 90% or better on written tests to state the principle of the guaiac test to detect hemoglobin, to define the purpose of the fecal occult blood test and to list causes of false positives and false negatives.

### Demonstrate Procedure/Skill under Direct Observation:

Perform the test for occult blood in feces, demonstrating 100% compliance with performance elements.

## Review Worksheets, Quality Control and Maintenance Logs for Complete Documentation:

Evaluate test results in the context of internal control steps. If acceptable, report. If results are questionable, reject and request repeat. Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A patient has vomited. The staff suspect blood in the emesis. Can the fecal hemocult test be used to test for hemoglobin in gastric specimens. Explain why or why not.



**BODY FLUIDS** 

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Range of urine (serum for some test systems) samples including those that are positive and negative

Test kit with internal controls

Positive and negative external controls

A procedure

OSHA-recommended personal protective equipment

Transfer pipettes

## **WORK TO BE PERFORMED**

Perform the test to detect pregnancy, human chorionic gonadotropin.

## PERFORMANCE CRITERIA

A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity from abnormal low, expected to abnormal high ranges. The time to result the array of five samples will depend on the particular test system and the nature of problems encountered. Normally, the tests may be resulted in ten minutes.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### Client Preparation:

1. Procedures require either urine (preferably first morning voided) or serum.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

### Assemble Reagents and Controls:

3. Assemble test kit. If refrigerated, allow to come to room temperature. Include transfer pipettes and labeled specimens.

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Ensure that the urine is not too dilute. Plasma samples are normally unacceptable for this test.

### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Remove the test pack or kits from protective wrapping.
- 6. Use transfer pipette to dispense the required drops of specimen into the sample well.



7. Read results immediately after the required incubation period. Evaluate in relationship to the results of the internal control mechanisms.

### Record, Evaluate and Report Results:

8. Interpret the results. Include the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

9. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to describe the principle of the immunoassay design of the qualitative determination of human chorionic gonadotropin, stating the limitations of the procedure, the limits of sensitivity and potential interfering substances.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

### Demonstrate Problem-Solving Skills:

Example: In reading the results of the test, one of the two internal procedural controls does not work. Suggest a corrective course of action.



1:0

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Five selected seminal fluids (may use simulations)

Microscope

Glass slides

A procedure

OSHA-recommended personal protective equipment

Biohazard container

Wet mount or Makler counting chamber

## **WORK TO BE PERFORMED**

Demonstrate the analysis and evaluation of seminal fluid.

## PERFORMANCE CRITERIA

A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity from abnormal low, expected to abnormal high ranges.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### Client Preparation:

1. Instructions to the client regarding the collection of seminal fluid requires the greatest degree of sensitivity and professionalism. Written protocols in addition to verbal explanation should be provided. Provide appropriate glass or plastic containers. Require specimen to be brought to the laboratory within an hour of collection.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble and Maintain Equipment:

3. Assemble microscope and glass slides.

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Specimen should be at room temperature and received in the laboratory within an hour of collection.

### Perform Procedure and Quality Control; Document and Evaluate:

5. Assess the physical characteristics of the sample to include appearance, volume and viscosity.



- 6. Using a wet mount or Makler counting chamber, prepare a duplicate system for counting and evaluating sperm motility. Screen for uniformity.
- 7. Prepare slides of fresh sperm. Stain and evaluate morphology. Supraviatal stains of fresh semen enable an evaluation of sperm viability.
- 8. Evaluate the smear for other cell populations. Evaluate for the presence of agglutination.
- 9. Perform chemical analyses as requested to include pH, fructose and acid phosphatase.

### Record, Evaluate and Report Results:

10. Evaluate controls as a decision element in relationship to accepting and subsequent reporting of sample results.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

11. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the diagnostic purposes for seminal fluid analysis; routines for specimen collection; and comparison of the appearance, volume, viscosity, motility, sperm concentration, morphology, viability, cell population and agglutination and pH in a normal as compared to a compromised state.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A seminal fluid has been collected and refrigerated: Evaluate and, if required, suggest a corrective course of action.



## **CONDITIONS OF PERFORMANCE**

### Given the following:

Fresh diarrhea sample

Slides

Stain such as methylene blue of direct preparations or Wright's stains of dried fecal material

Microscope with a 100 x oil immersion lens

A procedure

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Evaluate for the presence of fecal leukocytes.

## **PERFORMANCE CRITERIA**

A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity from abnormal low, expected to abnormal high ranges.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Instruct the patient to provide a sample of fresh diarrheal stool. Deliver to the laboratory within four hours.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment and Reagents:

3. Assemble glass slides, the appropriate stain for the type of specimen to be reviewed and a microscope.

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Diarrheal specimens need to be no more than four hours post voiding.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare slide with specimen.
- 6. Stain according to instructions.
- 7. Review for the presence of leukocytes.



### Record, Evaluate and Report Results:

8. Include the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

 Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.

## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test describing conditions in which fecal analysis to include fecal leukocytes might be diagnostic. State the significance of the presence of fecal leukocytes in the differential diagnosis of diarrhea. State the limitations of this qualitative test.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

### Demonstrate Problem-Solving Skills:

Example: Diarrheal stool from yesterday's diaper is sent to the laboratory to test for the presence of fecal leukocytes. Is the specimen acceptable? If not, suggest a corrective course of action.



HEMATOLOGY

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Automated counting instrument

Procedure manual

Reagents

Controls

Properly anticoagulated whole blood specimen

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Perform a complete blood count.

## **PERFORMANCE CRITERIA**

Maintenance protocols, calibrations, assessing control results, processing patient samples and evaluating patient results may take up to thirty minutes. The target values for cell identification must reflect agreement of 90% with published or refereed values. Criteria for acceptable performance for refereed analytes are:

erythrocyte count = target ±6% hematocrit = target ±6% hemoglobin = target ±7%; leukocyte count = target ±10% platelet count = target +10%

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Patient Preparation:

1. Procedure requires a labeled whole blood sample drawn in EDTA by capillary or venous puncture.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Maintain instrument on a daily, monthly or other basis as required by the manufacturer. Verify reagent quantities and dating. Prepare materials to include controls and whole blood anticoagulated with EDTA.

### Evaluate Sample/Specimen for Acceptability or Rejection:

 Evaluate the type and age of specimen, the additive, ratio of blood to additive, proper mixing and proper labeling. Mix specimen and check for obvious clots and lipemia.



### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Operate instrument. Verify electrical and start-up parameters.
- 6. Once primed, perform and verify controls. A minimum of two levels of control must be run each eight hours.
- 7. Identify specimens to run in the order of log or verify bar coding. Place controls intermittently within run and at the end of the run as specified by laboratory quality control policy. Proceed with run.

### Record, Evaluate and Report Results:

8. Review results for those specimens that are unreasonable, for example, results in which the hemoglobin and hematocrit or the hematocrit and the mean corpuscular hemoglobin concentrations do not match. Review results for samples that meet the laboratory's criteria to be rerun such as alert or panic values or for those specimens that require a manual morphology review or differential. Report alert or panic values recording time, date and to whom reported. Review in terms of reportable range and report results in the context of accepted quality control values.

## Segregate, Handle, Dispose or Recycle Chemical, Biohazardous and/or Infectious Waste:

9. Clean and shut down instrument according to specific manufacturer's instructions. Store or discard samples according to laboratory policy.

## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Tests of Principles:

Assess basic principles of operation, components, calibration, controls and maintenance. State age- and sex-related reference ranges. Competence is demonstrated by a score of 90% or better.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements including instrument maintenance and function checks.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

Proficiency testing for hematology requires a minimum of five samples per assessment to cover a full range of values that would be expected in unknown samples.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with standards for complete documentation.

### Demonstrate Problem-Solving Skills:

Example: Upon review, the quality control values for the low control are outside the laboratory's requirement of  $\pm 2$  standard deviations. Outline a course of action.



HEMATOLOGY

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Slides

Whole blood sample anticoagulated with EDTA

Blood stain reagents such as Wright, Wright-Gremsa or Romanowsky

OSHA-recommended personal protective equipment

Pencil

Biohazard container

Puncture-proof container

Buffer

Microscope

Oil

## **WORK TO BE PERFORMED**

Prepare and stain a blood smear.

## **PERFORMANCE CRITERIA**

An acceptable peripheral blood wedge smear is labeled, made and stained within fifteen minutes and displays the following characteristics:

- covers at least half the length of the glass slide terminating at least 0.5
   inch before the end of the slide
- is narrower than the slide on which it is made so that the side edges may be examined with the microscope
- spread smoothly with a gradual transition from thick to thin with no waves, streaks, troughs, holes or bubbles
- · terminates in a straight feathered end
- · is thin enough to allow proper fixation
- contains at least 10 low-power fields in which none of the erythrocytes overlap

After staining, the red blood cells should be salmon pink, leukocyte nuclei are purple with neutrophil granules pink-lavender in color, platelets are lilac with red-purple granules, eosinophils include orange granules and monocytes display gray ground glass cytoplasm with many tiny red to purple granules. An acceptable smear displays a minimum of artifact.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### **Patient Preparation:**

1. Procedure requires a labeled whole blood sample drawn in EDTA by capillary or venous puncture.



### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble slides; pencil; EDTA anticoagulated whole blood; surface disinfectant; biohazard container; puncture-proof container; blood stain reagents such as Wright, Wright-Giemsa or Romanowsky stain; and buffer.

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Obtain an anticoagulated whole blood sample and mix well. Evaluate the type and age of specimen, the additive, ratio of blood to additive, proper mixing and proper labeling. Check for clots.

### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Use precleaned slides or clean slides.
- 6. Place a clean slide on a flat surface.
- 7. Prepare the wedge smear. Compare the resulting smear with the performance criteria. If the smear is acceptable, place unique identifier, date and technician's initials on the slide.
- 8. Allow the smear to air dry.

#### Stain a Blood Smear:

- 9. Fix the cells to the slide if required by the procedure.
- 10. Stain a blood smear following the manufacturer's instructions by either flooding, dipping or using an automated stainer.
- 11. Assess the smear for readability. Remove excess stain from the back of the slide.
- 12. Allow slide to air dry.

### Record, Evaluate and Report Results:

13. Review slide under oil immersion to compare with the performance criteria.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazaardous and/or Infectious Waste:

14. Store the slide according to laboratory policy to include a minimum of two years.

## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Demonstrate competence by a score of 90% or better on written test to clarify the purpose of the blood smear and principles of each of the stains. List components seen in the blood smear and identify criteria for a properly prepared smear.

#### Demonstrate Procedure/Skill under Direct Observation:

Comply 100% with the selected performance elements of the procedure.

Demonstrate Successful Performance with a Proficiency Sample, Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.



Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with standards for complete documentation.

### Demonstrate Problem-Solving Skills:

Example: Under oil immersion, the nuclei of the neutrophils are indistinct and the granules appear washed out. What are possible explanations? Suggest a course of corrective action.



## **CONDITIONS OF PERFORMANCE**

### Given the following:

Stained slides

Microscope with a 100 x oil immersion lens

Oil

Procedure

Normal and abnormal stained blood smears

Lens paper

Differential counter

Puncture-proof sharps container

Worksheet

### **WORK TO BE PERFORMED**

Perform a differential white blood cell count on each smear.

### **PERFORMANCE CRITERIA**

Criteria for acceptable performance requires a minimum of five slides exhibiting a full range of values that describe morphology expected in patient specimens. A white blood cell differential identifying and classifying at least 100 consecutive leukocytes in a stained blood film is accomplished within three minutes each with the accuracyof the qualitative test to reflect agreement of  $\pm 10\%$  of the refereed or published value.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

1. Assemble normal and abnormal stained blood smears, microscope with oil immersion objective, immersion oil, lens paper, differential counter and puncture-proof sharps container.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

2. Evaluate the stained blood smears. Each should be reddish purple in color as established by previously standardized procedure and should cover at least one-half the length of the glass slide. The feathered edge displays a section of the smear in which none of the cells overlap.

#### Perform Procedure; Document and Evaluate:

- 3. Place stained smear face up on microscope stage and secure.
- 4. Use the low power 10 x objective to locate the feathered edge of the smear.
- 5. Bring the cells into focus.
- 6. Focus, using the fine adjustment, until cells can clearly be seen.
- 7. Open the diaphragm to allow maximum light into objective. Rotate objective, add oil and refocus using the oil lens.



- 8. Scan the slide on oil to observe the leukocytes.
- 9. Study the smear, identifying all five types of leukocytes, for immature, reactive or atypical lymphs; abnormal nucleated cells; and leukocyte inclusions. Estimate the leukocyte count from the stained blood smear for correlation with automated counts.
- 10. Count and classify 100 consecutive leukocytes and note morphology.

### Record, Evaluate and Report Results; Refer if Appropriate:

- 11. Record on the worksheet how many of each type of leukocyte are seen. As required by procedure, correct leukocyte counts for the presence of nucleated red cells or micromegakaryocytes, if observed, and comment on morphology.
- 12. Evaluate in context of patient reference ranges to accept and report or to refer.
- 13. Store slide according to laboratory policy.
- 14. Clean the oil immersion lens thoroughly using lens paper.

## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Demonstrate competence by a score of 90% or better on a written test to describe the purpose of the differential, each type of white cell and related possible pathology, the reference ranges for each type of cell, the morphology, the terms of the morphology and the criteria for referral of slides.

### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate competence by complying 100% with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

Demonstrate an accuracy on the differential count of agreement of 90% with the refereed or published values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Demonstrate competence through 95% compliance with documentation protocols.

#### Demonstrate Problem-Solving Skills:

Example: This white cell is large. The nuclear chromatin pattern appears delicate demonstrating clumping. Nucleoli are faint. Granules appear throughout the larger cytoplasm and on top of the nucleus. What is the most likely cell? Suggest a course of action.



**HEMATOLOGY** 

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Stained slide

Microscope with a low power, high power and an oil immersion lens Oil

A procedure

Lens paper

Differential counter

Puncture-proof sharps container

### **WORK TO BE PERFORMED**

Perform a review of red blood cell morphology.

### PERFORMANCE CRITERIA

Criteria for acceptable performance requires a minimum of five slides exhibiting a full range of values that describe morphology expected in normal and abnormal patient specimens. A normal morphology review is accomplished within three minutes per slide with the accuracy of the qualitative test to reflect agreement within ±10% of refereed or published descriptions. Ten to fifteen fields of approximately 200 cells each are examined.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

 Assemble normal and abnormal stained blood smears, microscope with oil immersion objective, immersion oil, lens paper, differential counter and punctureproof sharps container.

### Evaluate Sample/Specimen for Acceptability or Rejection:

Evaluate the stained blood smears. Each should be reddish purple in color as
established by previously standardized procedures and cover at least one-half the
length of the glass slide. The feathered edge should display at least 50% of the
cells that do not overlap.

#### Perform Procedure; Document and Evaluate:

- 3. Place stained smear face up on microscope stage and secure.
- 4. Use the low power 10 x objective to locate the feathered edge of the smear.
- 5. Bring the cells into focus.
- 6. Focus, using the fine adjustment, until cells can clearly be seen.
- 7. Open the diaphragm to allow maximum light into objective. Rotate objective, add oil and refocus using the oil lens.
- 8. Scan the slide on oil to study the erythrocytes.



- 9. Compare the erythrocyte morphology to the red blood cell indices.
- 10. Review erythrocytes in ten different fields. Note hemoglobin content. Record as normochromic or hypochromic. Review erythrocyte size and shape. Using standard nomenclature, record as normocytic, microcytic or macrocytic. If pathology exists, grade the affected cells (anisocytosis or poikilocytosis). Identify the presence of any inclusions.

## Record, Evaluate and Report Results; Refer if Appropriate:

- 11. Record observations on worksheet. Evaluate in relation to automated count and erythrocyte indices.
- 12. Evaluate in context of laboratory criteria and patient reference ranges to accept and report or to refer.
- 13. Store slide according to laboratory policy.
- 14. Clean the oil immersion lens thoroughly using lens paper. (Do not drag the high power objective through the oil).

## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Demonstrate competence with a score of 90% or better on a written test to describe the purpose of reviewing erythrocyte morphology; the reference ranges for each type of cell; the morphology and the terms to describe the morphology; cell sizes, shapes, color, possible inclusions and related pathology and the criteria for referral of slides.

### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate competence by complying 100% with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen, Matching Results to Recorded or Published Standards:

Demonstrate an accuracy on the erythrocyte review with an agreement of  $\pm 10\%$  when compared to refereed or published evaluations.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Demonstrate competence through 95% compliance with documentation protocols.

### Demonstrate Problem-Solving Skills:

Example: The hematocrit is 19%, the hemoglobin is 8 mg/dL, the MCHC is 33 g/dL and the MCV is 115 fL. What morphological picture is predicted? Suggest a course of corrective action.



### **CONDITIONS OF PERFORMANCE**

### Given the following:

Stained slide

Microscope with a 100 x oil immersion lens

Oil

Lens paper

Differential counter

Puncture-proof sharps container

## **WORK TO BE PERFORMED**

Estimate numbers and describe platelet morphology.

### PERFORMANCE CRITERIA

Criteria for acceptable performance requires a minimum of five slides exhibiting a full range of values that describe platelet numbers and morphology expected in patient specimens. A normal review is accomplished within three minutes per slide with the accuracy of the qualitative test to reflect agreement of  $\pm 10\%$  of the refereed (peer reviewed) or published value.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

1. Assemble normal and abnormal stained blood smears, microscope with oil immersion objective, immersion oil, lens paper, differential counter, puncture-proof sharps container and surface disinfectant.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

Evaluate the stained blood smears. Each should be reddish purple in color as
established by previously standardized procedures and cover at least one-half the
length of the glass slide. The feathered edge should display a section of the smear
where 50% of the cells overlap.

#### Perform Procedure; Document and Evaluate:

- 3. Place stained smear face up on microscope stage and secure.
- 4. Use the low power 10 x objective to locate the feathered edge of the smear.
- 5. Bring the cells into focus.
- 6. Focus, using the fine adjustment, until cells can clearly be seen.
- 7. Open the diaphragm to allow maximum light into objective. Rotate objective, add oil and refocus using the oil lens.
- 8. Scan the slide on oil to study the platelets.
- 9. Review the platelet morphology and compare to automated numbers and mean platelet volume.



- 10. Study the smear describing the platelet morphology number in ten different fields. Note abnormalities such as platelet sat elitism or giant platelets.
- 11. Count the number of platelets in ten oil immersions fields. The average number of platelets per oil immersion field times 20,000 approximates the platelet count. Report number estimates as adequate, decreased or increased and note morphology.

### Record, Evaluate and Report Results; Refer if Appropriate:

- 12. Record observations on the worksheet. Compare this number with the number of platelets from the electronic or manual count.
- Evaluate in context of patient reference ranges to accept and report or to refer.
- 14. Store slide according to laboratory policy.
- 15. Clean the oil immersion lens thoroughly using lens paper.

## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Demonstrate competence with a score of 90% or better on a written test to describe the purpose of reviewing platelet morphology; the reference ranges for platelet numbers; the morphology and the terms to describe the morphology and related pathology and the criteria for referral of slides.

### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate competence by complying 100% with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

Demonstrate an accuracy on the platelet review by  $\pm 10\%$  agreement when compared to refereed or published evaluations.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with documentation protocols.

### Demonstrate Problem-Solving Skills:

Example: On first slide review, ten consecutive fields are virtually devoid of platelets. What are possible explanations? Suggest a course of corrective action.



HEMATOLOGY

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Sedimentation tubes

Transfer pipette

Sample of venous blood collected in EDTA

Timer

Controls or duplicates

A procedure

OSHA-recommended personal protective equipment

Biohazardous/sharps container

Soap

## **WORK TO BE PERFORMED**

Perform an erythrocyte sedimentation rate test.

### PERFORMANCE CRITERIA

Depending on the system used, test preparation and reading may take up to ten minutes. The entire procedure may take up to 70 minutes to complete. The result of this test must be within ±5% of the target value.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### **Patient Preparation:**

1. Procedure requires a labeled whole blood sample drawn in EDTA by venous puncture.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble equipment and materials (sample of venous blood with appropriate anticoagulant, sedimentation tubes and rack, transfer pipette and timer).

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the type and age of specimen, the additive, ratio of blood to additive and proper mixing and labeling. Mix specimen and check for clots. Mix blood sample gently for two minutes.



### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Following protocol for Westergren, modified Westergren or Wintrobe:
  - a. If applicable, remove stopper on sedimentation vial and fill to the indicated mark.
  - b. Place sedimentation vials in rack on a level, vibration-free surface in a temperature controlled environment.
  - c. Set timer.
  - d. Read as directed by the procedure.

### Record, Evaluate and Report Results:

6. Record the sedimentation rate. Evaluate this result in the context of a control or a duplicate sample. Accept and report results or reject.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 7. Dispose of tube and vial in a biohazard/sharps container. Store or discard sample in keeping with laboratory policy.
- 8. Clean work area with surface disinfectant.
- 9. Remove gloves and discard into biohazard container.
- 10. Wash hands with soap.

## ASSESSMENT AND CREDENTIALING APPROACH

### Pass Written Test of Principles:

Demonstrate competence with a score of 90% or better on a written test to identify the principle of the erythrocyte sedimentation test and the relationship to disease. List properties of blood that affect the erythrocyte sedimentation rate and technical factors that may affect the result. State the reference values for the test.

### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate competence by complying 100% with essential performance elements.

### Demonstrate Successful Performance with a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

The sedimentation results must match the control or the duplicate within  $\pm 5\%$  of the target value.

### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with documentation protocols.

### Demonstrate Problem-Solving Skills:

Example: On Tuesday, the patient's ESR was reported as 5 mm/hour. On Wednesday, the same patient's ESR was reported as 45 mm/hour. Explain and suggest a corrective course of action, if required.



## **CONDITIONS OF PERFORMANCE**

### Given the following:

Whole blood anticoagulated

Supravital blue stain

Slides

Miller ocular microscope with oil immersion objective with or without ocular assistive devices (if available)

Immersion oil

Controls

A procedure

Use a Miller ocular, if available

OSHA-recommended personal protective equipment

Biohazard container

Counter

Puncture-proof sharps container

Soap

Lens paper

## **WORK TO BE PERFORMED**

Perform a reticulocyte count.

## PERFORMANCE CRITERIA

Criteria for acceptable performance requires a minimum of five slides exhibiting a full range of expected values. The reticulocyte procedure takes up to one hour to perform. The accuracy of the qualitative test reflects agreement within ±25% of the refereed value from the split sample or from published control values. (Manual methodologies perform in the range of 1% to 8%. The level of imprecision ranges from 20% to 40%.)

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### **Patient Preparation:**

1. Procedure requires a whole blood sample drawn in EDTA by capillary or venous puncture.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble supravital stain, glass slides, microscope, oil objective, immersion oil, counter, surface disinfectant, biohazard container and puncture-proof sharps container. Ocular device is optional.



### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the type and age of specimen, the additive, ratio of blood to additive and proper mixing and labeling. Mix specimen and check for clots.

### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Mix anticoagulated specimen with supravital stain. Incubate for fifteen minutes at room temperature. Remix.
- 6. Remix the blood and supravital stain. Prepare two wedge smears. Air dry.
- 7. Place stained smear face up on microscope stage and secure.
- 8. Use the low power 10 x objective to locate the feathered edge of the smear.
- 9. Bring the cells into focus.
- 10. Focus, using the fine adjustment, until cells can clearly be seen.
- 11. Raise the condenser and open the diaphragm to allow maximum light into objective. Rotate objective, add oil and refocus using the oil lens.
- 12. Scan the slide on oil to observe the stained erythrocytes.
- 13. View 500 red cells and count the reticulocytes within those red cells on one slide and then repeat with the second slide.

### Record, Evaluate and Report Results:

- 14. Record the results. The two counts should agree within ±10%.
- 15. Calculate the reticulocyte count and evaluate in relationship to controls. Accept and report results or reject.
- 16. Clean oil immersion objective carefully and thoroughly with lens paper.

## Segregate, Handle, Dispose or Recycle Chemical, Biohazardous and/or Infectious Waste:

- 17. Dispose of tubes, slides and stain in a biohazard/sharps container. Store sample according to laboratory procedure.
- 18. Clean work area with surface disinfectant.
- 19. Remove gloves and discard into biohazard container.
- 20. Wash hands with soap.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Demonstrate competence with a score of 90% or better on a written test to define a reticulocyte and to describe its pathological significance and to explain how the stain works and the reference ranges in health and in pathology.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate competence by complying 100% with essential performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

The reticulocyte count must agree within ±25% of the controls.

### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with documentation protocols.

#### Demonstrate Problem-Solving Skills:

Example: The reticulocyte count is 2% and the polychromasia on the Wright stained smear was 3+. Suggest an explanation and/or a course of corrective action.



**HEMATOLOGY** 

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

Patient history including patient age and a hemoglobin value Whole blood sample anticoagulated with EDTA Sickling reagent and controls OSHA-recommended personal protective equipment

Biohazard/sharps container Incubator

Soap

## **WORK TO BE PERFORMED**

Perform screening solubility tests for the presence of sickling hemoglobin.

### PERFORMANCE CRITERIA

Criteria for acceptable performance include a positive and a negative control. A minimum of five challenge samples must demonstrate a full range of values that describe results expected in patient specimens including negatives and positives. The procedure requires twenty minutes to perform.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Patient Preparation:

1. Procedure requires a whole blood sample drawn in EDTA by capillary or venous puncture.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble EDTA anticoagulated blood, sickling reagent and a positive and a negative control.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the type and age of specimen, the additive, ratio of blood to additive and proper mixing and labeling. Mix specimen and check for clots.

### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Mix the anticoagulated whole blood sample and the controls with the sickling reagent. Incubate according to manufacturer's instructions.
- 6. Evaluate and document the positive and negative control. Read the patient samples and document.



#### Record, Evaluate and Report Results:

7. Evaluate the patient result in the context of the control results. Report, repeat or reject.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 8. Store or dispose of sample according to laboratory policy. Clean work area with disinfectant.
- 9. Remove gloves and discard into biohazard/sharps container.
- 10. Wash hands with soap.

## ASSESSMENT AND CREDENTIALING APPROACH

### Pass Written Test of Principles:

Demonstrate competence with a score of 90% or better on a written test to explain the principle of the insolubility of hemoglobin S in its deoxygenated form and list other hemoglobins that demonstrate a positive solubility test.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate competence by complying 100% with performance elements.

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

The positive and negative controls must be correct and the patient samples must agree 100% with the refereed result (confirmed electrophoresis).

### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with documentation protocols.

#### Demonstrate Problem-Solving Skills:

Example: The patient's hemoglobin is 4.3 g/dL. Both the positive and negative controls are acceptable. The patient sample is negative. Suggest a corrective course of action, if appropriate.



## **CONDITIONS OF PERFORMANCE**

### Given the following:

Microhematocrit tubes

Calibrated and maintained centrifuge

Microhematocrit reader

Reagents

Materials

Supplies

Controls

A procedure

Capillary tubes (plain and with heparin)

Acrylic safety shield

Sealing clay or disposable plastic sealing caps

Anticoagulated venous blood (or commercially simulated blood)

Laboratory tissue

Sterile gauze

70% alcohol

Sterile and disposable lancets

Puncture-proof sharps container

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Perform a microhematocrit test including unknowns and controls. Evaluate, trouble-shoot and remediate. Repeat and/or report following established criteria.

## **PERFORMANCE CRITERIA**

Criteria for acceptable performance for the microhematocrit require results within 20 minutes including three levels of control and with test values within ±6% of target values. The five challenges must cover the full range of values that represent expected ranges in patient specimens to include results ranging from low abnormal, normal and high abnormal. All controls and unknown samples must be performed in duplicate, and the duplicates must agree within two reading units.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.



### Patient Preparation:

- 2. Procedure requires labeled whole blood samples drawn in EDTA by capillary or venous puncture.
- 3. If venous samples, fill two capillary tubes per sample of EDTA anticoagulated blood.
  - a. Mix the tube of blood thoroughly.
  - b. Remove cap from tube with an acrylic safety shield placed between laboratory personnel and tube.
  - c. Tilt the tube so that blood is very near the top edge of the tube.
  - d. Insert the tip of a plain capillary tube into the blood and fill three-quarters full by capillary action. If using the precalibrated tubes, fill to the line.
  - e. Wipe the outside of the filled capillary tube with tissue to remove excess blood.
  - f. Seal the capillary tube by placing the clean end into the tray of sealing clay in documented order or using plastic sealing cap. Place in hematocrit centrifuge.
  - g. Fill the second tube in the same manner.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

- 4. Assemble equipment and materials to include hand disinfectant, capillary tubes (plain and with heparin), acrylic safety shield, sealing clay or disposable plastic sealing caps, micohematocrit centrifuge, microhematocrit reader, tube of anticoagulated venous blood (or commercially available simulated blood), laboratory tissue, 70% alcohol, sterile gauze, sterile and disposable lancets, surface disinfectant, biohazard container and puncture-proof sharps container.
- 5. Prepare microhematocrit tubes with three levels of control.

### Evaluate Sample/Specimen for Acceptability or Rejection

6. Check to see if the interior sealing clay edge appears level in tubes. The specimen must demonstrate an absence of clots and hemolysis.

### Perform Procedure and Quality Control; Document and Evaluate:

- 7. Correctly place the microhematocrit tubes in the centrifuge in documented order. Fasten and secure both lids.
- 8. Set timer and adjust the speed if necessary.
- 9. Centrifuge for the prescribed time.
- 10. Allow centrifuge to come to a complete stop and unlock lids.
- 11. Read the hematocrit values using the supplied reader system.
- 12. Average the values from the two tubes and record the microhematocrit results. Duplicate must agree within two units.

### Record, Evaluate and Report Results:

13. Evaluate the patient results in relation to control values, troubleshoot, remediate or report according to published criteria.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 14. Discard capillary tubes and used lancets into a puncture-proof biohazard container for sharps.
- 15. Clean equipment and return to proper storage.
- 16. Clean the work area with surface disinfectant.
- 17. Remove gloves and discard into biohazard container and wash hands with hand disinfectant.



## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Test of Principles:

Demonstrate competence by a score of 90% or better to explain what the microhematocrit measures, to state the reference ranges and critical values for microhematocrit, to list the conditions that affect the microhematocrit value and contribute to sources of error (both technical and physiological) and to list precautions to be observed in performing the microhematocrit.

### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate competence by complying 100% with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

Perform spun hematocrits on five different unknown samples secured through proficiency samples, blind or split samples that represent abnormal low, normal and abnormal high values. All test results must agree within  $\pm 6\%$  of the target values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Demonstrate competence through 95% compliance with documentation protocols.

### **Evaluate Problem-Solving Skills:**

Example: The microhematocrit control values are within set criteria for acceptability; however, the values for one of the patient's results are 36% and 40%, respectively. Evaluate and suggest a corrective course of action.



## **CONDITIONS OF PERFORMANCE**

### Given the following:

Hemocytometer

Glass coverslips

Capillary pipette

Reservoir system

Microscope

Five blood samples anticoagulated with EDTA representing a full range of low, normal and high counts

Minimum of two levels of control, recalling the formula for calculating the white blood cell count

A procedure

Lens paper

70% ethyl or isopropyl alcohol

Gauze

Puncture-proof sharps container

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Demonstrate a manual white blood cell count and calculate the total number of cells.

## PERFORMANCE CRITERIA

Criteria for acceptable performance include a minimum of five challenges representing a range of values that describe results experienced in patient specimens and representing expected, low abnormal, normal and high abnormal examples. Each of two levels of control must fall within  $\pm 2$  standard deviations of the established mean. Each count must be completed within fifteen minutes with an accuracy of  $\pm 10\%$  of target values.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Patient Preparation:

1. Procedure requires a labeled whole blood sample drawn in EDTA by capillary or venous puncture.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.



### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble equipment and materials to include whole blood anticoagulated with EDTA, a hemocytometer with coverslip in a humid chamber, surface disinfectant, lens paper, 70% ethyl or isopropyl alcohol, a capillary pipette and reservoir system such as a unopette for white blood cell counts, microscope, gauze, biohazard container and puncture-proof sharps container.

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the type and age of specimen, the additive, ratio of blood to additive and proper mixing and labeling. Mix specimen and check for clots.

### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Select the appropriate micropipette and reservoir for performing a manual white blood cell count.
- 6. Mix sample and fill pipette from a capillary puncture or from a tube of EDTA anticoagulated blood.
- 7. Wipe excess blood from the outside of the capillary pipette with soft laboratory tissue.
- 8. Fill reservoir. Let equalize for the time required by the procedure.
- 9. Remix the contents of the reservoir. Discard four to five drops and charge both counting chambers.
- 10. Place hemocytometer into a humidified chamber. Cover and incubate to equilibrium.
- 11. Place hemocytometer on the microscope stage and secure.
- 12. Use low-power objective to bring ruled area into focus. Locate the nine white blood cell squares. Switch to high power and refocus.
- 13. Using the boundary rule, count the white cells.
- 14. Repeat, counting the opposite side of the hemocytometer matching side two within ±10% of side one. Average the two counts.
- 15. Recall formula and calculate the white blood cell count.
- 16. Repeat entire procedure with a minimum of two levels of control.

### Record, Evaluate and Report Results:

17. If controls are accepted and if test results are representative, report results with published reference range.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 18. Discard or store sample, controls and disposable materials according to laboratory policy. Disinfect hemocytometer and coverglass and return equipment to proper storage.
- 19. Clean work area with disinfectant.
- 20. Remove gloves and discard into biohazard container and wash hands.

## ASSESSMENT AND CREDENTIALING APPROACH

### Pass Written Test of Principles:

Demonstrate competence by a score of 90% or better on a written test to define leukocytopenia, leukocytosis and related pathologies; age- and sex-related reference ranges; principle of testing; and the function of each reagent.

### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate competence by complying 100% with essential performance elements.



Demonstrate Successful Performance with a Proficiency Sample, a blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

Proficiency at each assessment requires a minimum of five samples representing a full range as seen in patient results. Each sample must be performed in duplicate. The duplicates must agree within  $\pm 10\%$ . The average and reported values of each of the unknown patient samples must agree within  $\pm 10\%$  of the target values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with standards for complete documentation.

### Demonstrate Problem-Solving Skills:

Example: The following data are generated in the course of completing a manual white blood cell count. Suggest a corrective course of action.

SQUARE 1	SIDE 1	SIDE 2	
1	8	7	
2	9	7	
3	10	5	
4	9	8	
5	7	6	
6	9	5	
7	9	5	
8	10	9	
9	7	10	
TOTAL	78	62	



HEMATOLOGY

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

### Given the following:

EDTA, heparin or fluoride anticoagulated whole blood or capillary sample Hb-Direct System or HemoCue System or other hemoglobin analyzer Reagents

Cuvettes

Two or three levels of control
Puncture-proof sharps container
OSHA-recommended personal protective equipment
Biohazard container

## **WORK TO BE PERFORMED**

Perform a hemoglobin determination using a hemoglobin analyzer.

## PERFORMANCE CRITERIA

Criteria for acceptable performance include a minimum of five challenges representing a range of values that describe results seen in patient specimens representing low abnormal, normal and high abnormal examples. The determination should be completed within fifteen minutes with an accuracy of  $\pm 7\%$  of the target value. Before accepting test results, all control values must be within  $\pm 2$  standard deviations of the established mean.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

### **Patient Preparation:**

1. Procedure requires a labeled whole blood capillary or venous sample collected in an approved anticoagulant for the analyzer method.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

- Assemble equipment and materials to include an Hb-Direct System, HemoCue System or other hemoglobin analyzer; unexpired cuvettes and/or reagents; two or three levels of control; biohazard container; and puncture-proof sharps container.
- 4. Turn on instrument to warm up. Perform and record preventive maintenance. Calibrate or standardize the instrument according to manufacturer's directions.



### Evaluate Sample/Specimen for Acceptability or Rejection:

5. Inspect whole-blood specimen and reject if sample appears clotted. Inspect capillary and/or cuvette devices and reject if sample appears to have formed air bubbles or if there is incomplete filling.

### Perform Procedure and Quality Control; Document and Evaluate:

- 6. Wipe excess blood and fingerprints from the outside of the collection device being careful not to touch the open end of the device.
- 7. Insert the filled capillary tube into the instrument's photometer system.
- 8. Read the hemoglobin value from the display and record.
- 9. Perform the same procedure with two or three levels of control and record.

### Record, Evaluate and Report Results:

10. Evaluate sample results in relation to control values. If control values are within accepted range, record and report test results.

## Segregate, Handle, Recycle and Dispose of Chemical Biohazardous and/or Infectious Waste:

- 11. Discard all contaminated materials into biohazard containers and sharps containers as required.
- 12. Return all equipment to proper storage.
- 13. Wipe counters with disinfectant.
- 14. Remove and discard gloves into biohazard container.
- 15. Wash hands with disinfectant.

## ASSESSMENT AND CREDENTIALING APPROACH

### Pass Written Test of Principles:

Demonstrate competence with a score of 90% or better on a written test to explain the principle of instrument operation, limits of linearity and other operations, chemical reactions, age- and sex-related reference ranges and the purpose of hemoglobin testing and related pathologies.

### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate competence by complying 100% with essential performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

Determine hemoglobin concentration of a minimum of five samples matching target values ±7%.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Demonstrate competence through 95% compliance with documentation protocols.



### Demonstrate Problem-Solving Skills:

Example: Evaluate the following findings in a male and suggest a course of action. The reference range is for males.

### HEMOGLOBIN RESULTS mg/dL

	Abnormal High Control Value	Abnormal Hign Control ± 2SD	Normal Control Value	Normal Control ± 2 SD	Abnormal Low Control Value	Abnormal Low Control ± 2 SD	Sample	Reference Range
Hemoglobin	1	1	1	1	8	6	1	1
mg/dL	9.4	6.9-17.7	5.0	2.6-13.2	.1	.6-7.1	7.6	2.0-15.8



## **CONDITIONS OF PERFORMANCE**

### Given the following:

Values for hemoglobin, hematocrit and the red blood cell count from five different samples representing a range of low, normal and high values Age- and sex-related reference ranges

Corresponding peripheral blood smears

Formulae for the mean corpuscular hemoglobin, the mean corpuscular hemoglobin concentration and the mean corpuscular volume

### **WORK TO BE PERFORMED**

Calculate and report the erythrocyte indices indicating the standard units of measure. Evaluate in relation to sex- and age-related reference ranges for these parameters. Correlate indices with peripheral blood film.

## PERFORMANCE CRITERIA

Criteria for acceptable performance require the completion of the calculations and the peripheral smear reviews in 35 minutes with an accuracy of 100%.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### **Patient Preparation:**

1. Requires data and peripheral smears from previously analyzed samples.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Calculation and review of peripheral smear may be performed away from analytical space in a safe environment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble hemoglobin, hematocrit and erythrocyte count data from a minimum of five samples, related peripheral blood smears and a microscope with 100 x oil immersion lens.

## Evaluate Sample Data Prior to Calculations for Acceptability or Rejection:

4. Assess the relationship between the hemoglobin and hematocrit values as provided.

### Perform Procedure and Quality Control; Document and Evaluate:

5. Recall formulae and calculate the mean corpuscular hemoglobin, the mean corpuscular hemoglobin concentration and the mean corpuscular volume. Correlate with peripheral blood smears.



### Record, Evaluate and Report Results:

6. Evaluate calculated results in relation to peripheral smears. Reject or report.

## **ASSESSMENT AND CREDENTIALING APPROACH**

### Pass Written Tests of Principles:

Pass a written test with a score of 90% or better to state and demonstrate the formulae for each of the three indices, quality control uses of the erythrocyte indices values, sex- and age-related reference ranges for the indices and common pathology associated with indices patterns.

### Demonstrate Procedure/Skill under Direct Observation:

Assess data, perform calculations, correlate with peripheral blood smear and reject or report with 100% accuracy.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Demonstrate competence through 95% compliance with documentation protocols.

### Demonstrate Problem-Solving Skills:

Example: The following data were presented for calculation of erythrocyte indices. Evaluate and suggest a course of action, if appropriate.

	HEMOGLOBIN g/dL	HEMATOCRIT %	RED BLOOD CELL COUNT #/cumm
1	16.9	49.5	5.26
2	9.1	29.5	48.00
3	10.0	48.3	5.45
4	13.0	39.0	4.33
5	18.1	52.6	53.00



## **CONDITIONS OF PERFORMANCE**

### Given the following:

Hemocytometer

Cover slips

S diluting system including lysing reagent such as 1% ammonium oxalate Microscope

Minimum of five labeled capillary or venous samples anticoagulated with EDTA and representing a full range of values to include abnormal low values within reference interval or normal values and abnormal high counts

Minimum of two levels of control

Recall the formula for calculating the final platelet count

A procedure

Acrylic safety shield

Test tube rack

Petri dish

Cotton ball moistened slightly with water

Lens paper

70% alcohol

Hand tally counter

Puncture-proof container for sharps

Biohazard container

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Demonstrate a manual platelet count. Calculate and reconcile with blood smear results and report the total number of platelets.

## PERFORMANCE CRITERIA

Criteria for acceptable performance include completing counts using a minimum of five challenges and two controls. The set of challenges shall represent a full range of target values that describe patients in states of health and pathology and demonstrate results within the expected reference interval, low abnormal and high abnormal examples. The two controls must fall within  $\pm 2$  standard deviations. Each count must be completed within fifteen minutes with an accuracy of  $\pm 25\%$  of target values.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### **Patient Preparation:**

1. Procedure requires a labeled whole blood sample drawn and well mixed in EDTA by capillary or venous puncture.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble equipment and materials to include hand disinfectant, EDTA anticoagulated blood sample, acrylic safety shield, hemacytometer with cover glass, test tube rack, diluting system for platelet count, microscope, petri dish, cotton ball moistened slightly with water, lens paper, 70% alcohol, hand tally counter, surface disinfectant, biohazard container and puncture-proof sharps container.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the type and age of specimen, the additive, the ratio of blood to additive and proper mixing and labeling. Mix specimen and check for clots.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Place a clean hemacytometer cover glass over a clean hemacytometer.
- 6. Prepare a 1:100 dilution of anticoagulated whole blood with ammonium oxalate using a Thoma pipette or a self-filling, self-diluting system.
- 7. Charge the hemacytometer and place in a moist environment for fifteen minutes.
- 8. Place the hemacytometer on the microscope stage carefully and securely.
- 9. Use the low power objective to bring the ruled area into focus.
- 10. Locate the large central square.
- 11. Rotate the high power objective into position carefully and focus with the fine adjustment knob until lines are clear.
- 12. Count the platelets in the entire center square of the ruled area. Use the boundary rule.
- 13. Repeat on the other side of the hemacytometer. The two sides must match ±10%. Average the results of the two sides.
- 14. Calculate the platelet count.
- 15. Duplicates must match ±10% and the two quality control counts must match ±25% of the target values. Evaluate these findings in relationship to the related peripheral blood smear.

#### Record, Evaluate and Report Results:

16. Record patient and control results including the correct units of measure. Evaluate patient results in relation to control values. Troubleshoot, remediate or report according to published criteria.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

17. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with disinfectant.



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# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on written test to explain the origin and function of platelets in hemostasis and to list age- and sex-related reference ranges, factors affecting platelets in related pathologic conditions such as thrombocytopenia or thrombocytosis and precautions to take when performing platelet counts. Describe potential sources of error.

### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. Under the direct observation of authorized personnel, demonstrate the procedure for counting platelets manually to include required calculations; the complete and accurate evaluation of controls, calculations and test values; and the reporting of results.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Demonstrate an accuracy of  $\pm 25\%$  of the target value on a minimum of five different unknown samples secured through proficiency samples or blind or split samples that represent abnormal low, expected reference intervals and abnormal high values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The manual platelet count yielded 80.000/mm<sup>3</sup>. The platelet estimate on the Wright's stained peripheral blood smear is 165,000 mm<sup>3</sup>. Assess these findings and suggest a course of corrective action.



## **COAGULATION/HEMOSTASIS**

## **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Five unknown whole-blood samples\* collected in correctly adjusted buffered sodium-citrated anticoagulant and the resulting centrifuged plasma

Minimum of two levels of control (normal and abnormal)

Patient and control reference interval

Partial thromboplastin activator

Calcium chloride reagents

Reaction vessel

Optical or electromechanical sensor or photo optical system

Temperature control

Timing device

A procedure

Fresh citrated plasma

Distilled water

Laboratory tissue

Test tube rack

Temperature-controlled reaction vessel

Pipettes

OSHA-recommended personal protective equipment

Biohazard container

# **WORK TO BE PERFORMED**

Perform an activated partial thromboplastin test including unknowns and controls; evaluate and troubleshoot; and remediate, repeat and/or report following established criteria.

# PERFORMANCE CRITERIA

Criteria for acceptable performance for the activated partial thromboplastin time include obtaining results within one hour with a minimum of two levels of control and with five test values within  $\pm 15\%$  of the target value. The samples must demonstrate a full range of values that describe results expected in patient samples. If the tests are performed manually, the patient samples and controls must be run in duplicate. If specimens are run in duplicate, the results of the pair must agree within  $\pm 10\%$ .



<sup>\*</sup>The five unknown samples must include one very high abnormal and one intermediate high abnormal to represent the therapeutic range when test results are used to monitor the effects of heparin anticoagulant therapy.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Patient Preparation:

1. Account for patient medications such as heparin that might affect the activated partial thromboplastin time test results; anticoagulant to whole blood ratios; order of collection in relation to other tubes with or without additives; and conditions of specimen temperature, storage and transport.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble and calibrate equipment (optical or electromechanical sensor or photo optical system, partial thromboplastin activator, calcium chloride reagents, fresh citrated plasma, normal and abnormal controls, distilled water for reconstituting controls, biohazard container, surface disinfectant, laboratory tissue, hand disinfectant, test tube rack, temperature-controlled reaction vessel, pipettes and timing devices).

## Evaluate Sample/Specimen for Acceptability or Rejection:

4. Procedure requires the centrifuged plasma resulting from a whole-blood sample be drawn in tubes containing volume-adjusted buffered sodium citrate anticoagulant. The specimen must meet the following criteria: anticoagulant to whole-blood ratios appropriately adjusted to patient hematocrit, absence of clots, hemolysis, lipemia or an icteric sample. The time of collection to time of testing must not exceed the outer limits of established criteria.

## Perform Procedure and Quality Control; Document and Evaluate:

- 5. Verify operating parameters such as temperature, calibrations, linearity as required; reconstitute reagents and controls as required; and label or otherwise uniquely identify.
- 6. Place patient plasma and controls in correct vessels and activate system according to procedure.

#### Record, Evaluate and Report Results:

- 7. Record sample and control results.
- 8. Evaluate the patient results in relation to control values, troubleshoot, remediate or report according to published criteria.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 9. Clean and return all equipment to proper storage.
- 10. Dispose of all sharps and contaminated articles in biohazard containers.
- 11. Wipe counter with surface disinfectant.
- 12. Remove gloves and discard into biohazard container.
- 13. Wash hands with hand disinfectant.



# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Demonstrate competence with a score of 90% or better on a written test to explain the principle of the activated partial thromboplastin test; considerations surrounding the collection, storage and transport of this specimen; the role of the contact activation factors in blood coagulation; the interpretation and correlation of the activated partial thromboplastin time test results; interfering substances and other sources of error; and precautions to take in performing the test.

#### Demonstrate Prodedure/Skill under Direct Observation:

Demonstrate the procedure under direct observation of authorized personnel to include the complete and accurate evaluation of controls and test values and the reporting of test results.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen, Matching Results to Recorded or Published Standards:

Demonstrate an accuracy of  $\pm 15\%$  of the target value performance on a minimum of five different unknown samples secured through proficiency samples or blind or split samples that represent abnormal low, normal and abnormal high values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Demonstrate competence through 95% compliance with documentation protocols.

#### Demonstrate Problem-Solving Skills:

Example: The activated partial thromboplastin test result was 98.7 seconds and the control was 32.3 seconds with published reference interval equal to 25-37 seconds. The prothrombin test results and controls were within reference intervals. The patient is on no anticoagulation therapy and is taking no other medication that has been associated with a prolonged APTT. Outline a recommended course of further evaluation and action.



# **COAGULATION/HEMOSTASIS**

# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Five unknown whole-blood samples collected in correctly adjusted anticoagulant-buffered sodium citrate and the resulting centrifuged plasma

Controls (normal and abnormal)

Reaction vessel

Optical or electromechanical sensor or photo optical system (fibrometer-electromechanical device, optical endpoint instrument, centrifuge)

Temperature control

Timing devices

A procedure

Exogenous thrombin

Fresh citrated plasma

Distilled water

Laboratory tissue

Hand soap

Test tube rack

Temperature-controlled vessel

**Pipettes** 

OSHA-recommended personal protective equipment

Biohazard container

# **WORK TO BE PERFORMED**

Perform the test to quantitate thrombin times in five unknowns with a control. Evaluate, troubleshoot, remediate, repeat and/or report following established criteria.

# **PERFORMANCE CRITERIA**

Criteria for acceptable performance for the quantification of thrombin time include obtaining results within one hour using five unknowns with values within  $\pm 20\%$  of the target values. The unknown samples must demonstrate a full range of values that describe results in health and in disease. If the tests are performed manually, the unknown samples and controls must be run in duplicate. If specimens are run in duplicate, the pairs of results must agree within  $\pm 10\%$ .



# **COAGULATION/HEMOSTASIS**

## **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Five unknown whole-blood samples\* collected in correctly adjusted buffered sodium-citrated anticoagulant and the resulting centrifuged plasma

Minimum of two levels of control (normal and abnormal)

Patient and control reference interval

Thromboplastin-calcium chloride reagent and its international sensitivity index

Reaction vessel

Optical or electromechanical sensor or photo optical system

Fibrometer (electromechanical), optical endpoint instrument or centrifuge

Temperature control

Timing device

A procedure

Fresh citrated plasma

Distilled water

Biohazard container

Laboratory tissue

Test tube rack

Temperature-controlled reaction vessel

**Pipettes** 

OSHA-recommended personal protective equipment

Biohazard container

# **WORK TO BE PERFORMED**

Perform a prothrombin time test including unknowns and controls. Evaluate and troubleshoot. Remediate, repeat and/or report following established criteria. Calculate the International Normalized Ratio (INR) and report.

# **PERFORMANCE CRITERIA**

Criteria for acceptable performance for the prothrombin time and calculated INR include reporting results within one hour with a minimum of two levels of control and with five test values within  $\pm 15\%$  of the target value. The samples must demonstrate a full range of values that describe results expected in patient samples. If the tests are performed manually, the patient samples and controls must be run in duplicate. If specimens are run in duplicate, the results of the pair must agree within  $\pm 10\%$ .



<sup>\*</sup>The five unknown samples must include one very high abnormal and one intermediate high abnormal to represent therapeutic range when test results are used to monitor the effects of oral anticoagulant therapy.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen, Matching Results to Recorded or Published Standards:

Demonstrate an accuracy of  $\pm 20\%$  performance on a minimum of five different unknown samples secured through proficiency samples, blind or split samples that represent abnormal low, normal and abnormal high values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Demonstrate competence through 95% compliance with documentation protocols. Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

### Demonstrate Problem-Solving Skills:

Example: The fibrinogen result is 780 mg/dL. The reference interval is reported as 195-440 mg/dL. The range of linearity is 0-560 mg/dL. Evaluate and suggest a corrective course of action.



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# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Patient Preparation:

1. Account for anticoagulant to whole-blood ratios; order of collection in relation to other tubes with or without additives; and conditions of specimen temperature, storage and transport.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble and calibrate equipment (fibrometer, optical endpoint instrument, centrifuge, thrombin reagent, fresh citrated plasma, normal control, distilled water for reconstituting control and reagent, biohazard container, surface disinfectant, laboratory tissue, hand soap, test tube rack, temperature-controlled reaction vessel, pipettes, timing device and proper buffer for sample and control dilutions).

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the plasma for clots, excessive hemolysis, icterus or lipemia. Note heparin levels > 1 U/mL. Verify that the sodium citrate anticoagulated sample was not the first tube drawn and that indwelling catheters were initially flushed before the specimen was drawn.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Verify operating parameters such as temperature, calibrations and linearity as required; reconstitute reagents and controls as required; and label.
- 6. Place patient plasma and controls in correct vessels; activate system according to procedure.

#### Record, Evaluate and Report Results:

7. Includes the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands with soap.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to describe fibrinogen's role in coagulation, related pathological conditions when it may be elevated or decreased, the principle of the test procedure used and interferences.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the procedure under direct observation of authorized personnel to include the complete and accurate evaluation of controls and test values and the reporting of test results.



# **COAGULATION/HEMOSTASIS**

# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Five unknown whole-blood samples collected in correctly adjusted anticoagulant-buffered sodium-citrated volume and the resulting centrifuged plasma

Normal control of known fibrinogen concentration

Calibration plasma

Fresh citrated plasma

Reaction vessel

Optical or electromechanical sensor or photo optical system (fibrometer, optical endpoint instrument or centrifuge)

Temperature control

Temperature-controlled reaction vessel

Timing device

A procedure

Thrombin reagent

Distilled water

Laboratory tissue

Hand soap

Test tube rack

**Pipettes** 

Proper buffer for sample and control dilutions

OSHA-recommended personal protective equipment

Biohazard container

# **WORK TO BE PERFORMED**

Perform a test to quantitate fibrinogen levels in five unknowns with a normal control of known fibrinogen concentration. Evaluate, troubleshoot, remediate, repeat and/or report following established criteria.

# **PERFORMANCE CRITERIA**

Criteria for acceptable performance for the quantification of fibrinogen include obtaining results within one hour on a control and five unknowns with values within  $\pm 20\%$  of the target values. The unknown samples must demonstrate a full range of values that describe results in health and in disease. If the tests are performed manually, the unknown samples and controls must be run in duplicate. If specimens are run in duplicate, the pairs of results must agree within  $\pm 10\%$ .



# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Demonstrate competence with a score of 90% or better on a written test to explain the principle of the prothrombin time test; considerations surrounding the collection, storage and transport of this specimen; the role of prothrombin in blood coagulation; the interpretation and correlation of the prothrombin time test results; interfering substances and other sources of error; and precautions to take in performing the test.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the procedure under direct observation of authorized personnel to include the complete and accurate evaluation of controls and test values and the reporting of test results.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen, Matching Results to Recorded or Published Standards:

Demonstrate an accuracy of  $\pm 15\%$  within target values, performance on a minimum of five different unknown samples secured through proficiency samples or blind or split samples that represent abnormal low, normal and abnormal high values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Demonstrate competence through 95% compliance with documentation protocols.

#### Demonstrate Problem-Solving Skills:

Example: A anticoagulated whole-blood specimen has arrived in the laboratory for a prothrombin time test. The specimen has been collected in ethylene-diamine-tetraacetic acid (EDTA). Evaluate the specimen, state the reasons for accepting or rejecting the specimen and develop a plan of action.



# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Patient Preparation:

1. Account for patient medications such as warfarin affecting the prothrombin test results; hematocrit; anticoagulant to whole-blood ratios; order of collection in relation to other tubes with or without additives; and conditions of specimen temperature, storage and transport.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

# Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble and calibrate equipment (fibrometer - electromechanical, optical endpoint instrument or centrifuge; thromboplastin; phospholipid and calcium reagent; fresh citrated plasma; normal and abnormal controls; distilled water for reconstituting controls; biohazard container; surface disinfectant; laboratory tissue; hand disinfectant; test tube rack; temperature-controlled reaction vessel; pipettes; and timing devices).

## Evaluate Sample/Specimen for Acceptability or Rejection:

4. The specimen must meet the following criteria: anticoagulant to whole-blood ratios appropriately adjusted to patient hematocrit and the absence of clots, hemolysis, lipemia or an icteric sample. The time of collection to time of testing or storage must not exceed the upper limits of established criteria.

### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Verify operating parameters such as temperature, calibrations and linearity as required; reconstitute reagents and controls as required; and uniquely identify.
- 6. Place patient plasma and controls in correct vessels and activate system according to procedure.

#### Record, Evaluate and Report Results:

- 7. Record sample and control results.
- 8. Evaluate patient results in relation to control values and troubleshoot, remediate or report according to published criteria.
- 9. Calculate INR.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

- 10. Clean and return all equipment to proper storage.
- 11. Dispose of all sharps and contaminated articles in biohazard containers.
- 12. Wipe counter with surface disinfectant.
- 13. Remove gloves and discard into biohazard container.
- 14. Wash hands with hand disinfectant.



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# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### **Patient Preparation:**

1. Account for anticoagulant to whole-blood ratios; order of collection in relation to other tubes, with or without additives; and conditions of specimen temperature, storage and transport.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble and calibrate equipment (fibrometer-electromechanical device, optical endpoint instrument, centrifuge, exogenous thrombin, fresh citrated plasma, normal and abnormal controls, distilled water for reconstituting control and thrombin reagent, biohazard container, surface disinfectant, laboratory tissue, hand soap, test tube rack, temperature-controlled reaction vessel, pipettes and timing devices).

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the plasma for clots, excessive hemolysis, icterus or lipemia. Note heparin levels > 1 U/mL. Verify that the sodium citrate anticoagulated sample was not the first tube drawn and that indwelling catheters were initially flushed before the specimen was drawn.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Verify operating parameters such as temperature, calibrations, linearity as required; reconstitute reagents and control as required; and label.
- 6. Place patient plasma and control in correct vessels and activate system according to procedure.

#### Record, Evaluate and Report Results:

7. Evaluate control results prior to reporting test results. Report if criteria are met.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to describe the relationship of thrombin time to fibrinogen, heparin or fibrinogen degradation products; related pathological conditions when it may be elevated; the principle of the test procedure used and interferences.

### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the procedure under direct observation of authorized personnel to include the complete and accurate evaluation of controls and test values and the reporting of test results.



Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Specimen, Matching Results to Recorded or Published Standards:

Demonstrate an accuracy of ±20% performance on a minimum of five different unknown samples secured through proficiency samples and blind or split samples that represent abnormal low, normal and abnormal high values.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Demonstrate competence through 95% compliance with documentation protocols. Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

#### Demonstrate Problem-Solving Skills:

Example: The thrombin control result is four standard deviations from the mean. All five of the test results are also prolonged. If appropriate, recommend corrective action.



# COAGULATION/HEMOSTASIS

# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Five unknown samples of whole blood mixed with bovine thrombin and trypsin inhibitor and the resulting centrifuged serum

Glycine-buffered saline diluent

Latex suspension of immunoglobulins raised against the fibrinogen degradation products

Latex particles coated with polyclonal antibodies

Negative and positive control sera

Timing device

A procedure

Reaction cards

Glass slides

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Perform a semiquantitative test for fibrin(ogen) degradation products in five unknowns with a positive and a negative control; evaluate results; and repeat and/or report.

# PERFORMANCE CRITERIA

Criteria for acceptable performance require that the controls resulted as expected and that the results of the latex agglutination test are interpreted correctly. The five unknown samples must represent the full range of reactivity of possible patient results.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Collect fresh whole-blood sample and mix immediately with bovine thrombin and trypsin inhibitor to yield rapid and complete clotting. If heparin therapy is expected, add reptilase.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.



#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble client serum, reaction cards or glass slides, latex particles coated with polyclonal antibodies, positive and negative controls and a timing device.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Reject hemolyzed specimens.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Assemble prepared serum, prepare required dilutions and place one drop of unknowns and controls onto plates or cards.
- 6. Add the latex suspension of antibodies.
- 7. Mix gently by rocking.

#### Record, Evaluate and Report Results:

- 8. Read reactions within specified time frame and record results.
- 9. Evaluate controls as a decision element in relationship to accepting and subsequent reporting of sample results.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

10. Clean work area with disinfectant. Remove gloves and discard into biohazard container. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Tests of Principles:

Competence is demonstrated by a score of 90% or better on a written test to describe the four most common fibrin degradation products, the principle of the test for fibrin degradation products, the purpose of the trypsin inhibitor, expected results in health and in disease and common technical difficulties associated with the testing. Include the relationship of fibrinogen degradation products to acquired defects of platelet adhesion, possible peripheral blood findings, disseminated intravascular coagulation and the results of the D-dimer test.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample, Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards, for example, as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The unknown sample and both of the controls are negative. If applicable, suggest an appropriate corrective action.



### **COAGULATION/HEMOSTASIS**

# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Puncture lancet such as a simplate retractable bleeding time device

Blood pressure cuff

Stop watch

Alcohol

Filter paper or other blotting material

A procedure

Sharps container

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate the Ivy bleeding time test.

### PERFORMANCE CRITERIA

Criteria include the accurate identification of the patient, use of sterile technique and proper use of equipment. Depending on the protocol, the procedure may take 30 to 45 minutes to complete.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. After confirming the request and identification of the client, approach the client, introduce yourself and provide for the privacy of the client. Explain the procedure to the client, family member or care giver.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment:

3. Verify the working conditions of the equipment such as blood pressure cuff and timer and the sterility of the lancet devices.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Note if client is taking any medications that might prolong the bleeding time beyond the expected reference intervals.

#### Perform Procedure; Document and Evaluate:

5. Place the blood pressure cuff around the upper arm and inflate to 40 mm Hg. Hold this pressure constant throughout the procedure.



- 6. Select a site free of visible surface capillaries; clean with alcohol and allow to air dry.
- 7. Place the lancet device firmly on the site to deliver a 3 mm deep incision and trigger.
- 8. Blot the wound every 30 seconds with filter paper taking care that the paper does not contact the wound.
- 9. Continue blotting in 30-second intervals until the bleeding stops.

#### Record, Evaluate and Report Results:

- 10. Record and report the time the bleeding ceases. Make notations of client identification and time intervals of when the blotting begins and stops on the filter paper.
- 11. Clean the puncture site; ensure that all bleeding has stopped. Apply pressure if required. Apply a sterile bandage.
- 12. Restore client to comfortable and safe position. If appropriate, leave signal cord, telephone and fresh water close at hand; return bed to lowest position; remove any screening used for privacy; and remove any soiled linens or materials.
- 13. Thank the client for cooperation.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste

14. Clean work area with disinfectant and discard lancet device into sharps container. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to describe the principle of the bleeding time test, reference intervals, precautions to take during testing and interpretation of the test.

#### Demonstrate Procedure/Skill under Direct Observation:

Under the direct observation of authorized personnel, perform a bleeding time test. Successful demonstration requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample, Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The patient states that he takes one aspirin a day as prophylactic therapy. The bleeding stopped after thirteen minutes. What course of action may be appropriate?



# SKILL STANDARD

# CONDITIONS OF PERFORMANCE

#### Given the following:

Any inoculum (stock culture, controls, treated or mixed culture) of representative anaerobes

Enterobacteriaceae

Gram positive bacilli

Gram positive cocci

Gram negative cocci

Miscellaneous gram negative bacteria

Variety of enriched, selective or differential media

Inoculating loops and holders

Incinerator

Incubator

A procedure

Sterile swabs

Blood agar

Variety of selective agar

Waterproof marker

Test tube rack

Thermometer

Flask

Beaker

Bottle

Temperature-controlled refrigerator

OSHA-recommended personal protective equipment

Biohazard container

# **WORK TO BE PERFORMED**

Select from a variety of enriched, selective or differential media and inoculate a series of agar plates representing anaerobes, *Enterobacteriaceae*, gram positive bacilli, gram positive cocci, gram negative cocci and miscellaneous gram negative organisms with a swab and/or with an inoculating loop. Streak for isolation.

# PERFORMANCE CRITERIA

Criteria for acceptable performance includes compliance with bloodborne pathogens standards, demonstration of sterile technique, selection of the appropriate media and streaking for isolation in one minute without error on day one. On day two, visual discrimination for isolated colony morphology on routine media is demonstrated. A minimum of five challenge samples must demonstrate a full range of samples to include anaerobes, *Enterobacteriaceae*, gram positive bacilli, gram positive cocci, gram negative cocci and various miscellaneous gram negative bacteria.



# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. If specimens are collected, refer to the representative skill standard in Test Management.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble equipment and materials to include an incubator set at 35° Celsius; thermometer immersed in glycerin in a flask, beaker or bottle in the incubator; temperature-controlled refrigerator for storing culture media; incinerator; inoculating loops and holders; sterile swabs; blood agar, trypticase soy broth and a variety of other selective media; waterproof marker; and test tube rack. Bring media to room temperature. Temperature should be observed and recorded daily.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate any culture material to demonstrate inoculation and evaluate colony morphology to verify identification and isolation.

#### Perform Procedure; Document and Evaluate:

- 5. Preparing the work station:
  - a. Disinfect the work area.
  - b. Turn on the incinerator.
  - c. Select the media that provide the most favorable conditions for the suspected pathogens on which to plate the inoculum. Evaluate for acceptability of the media and label the bottom of the plate with a marker.
- 6. Inoculation:
  - a. Demonstrate standard sterile inoculation techniques including loop flaming, swab rolling, media stabbing and/or overlap and streaking for isolation (triple streak).
  - b. Demonstrate technique for carry over and streak to achieve isolation.
- 7. Place inoculated plate upside down in a temperature and humidity-controlled incubator.
- 8. In the case of anaerobes, provide a CO<sub>2</sub> incubator or a reduced-oxygen environment.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

9. Clean work area with disinfectant. Remove gloves. Wash hands.



#### Record, Evaluate and Report Results:

- 10. On day two, evaluate plates for isolation. Discriminate between the following visual colony morphology on routine media:
  - a. Gram positive and gram negative
  - b. Staphylococci, streptococci and gram positive bacilli
  - c. Enteric and fastidious gram negative bacilli
  - d. Lactose fermenting and non-lactose-fermenting bacilli on EMB, MacConkey, Hektoen, SS agar and XLD
  - e. Growth and no growth
  - f. Bacteria, yeasts and molds
  - g. Pseudomonas and enteric bacilli
  - h. Alpha, beta and gamma hemolytic colonies
  - i. Campylobacter and other unusual gram negative bacilli
- 11. Discriminate between the following odors associated with colony morphology on routine media:
  - a. Proteus species
  - b. Pseudomonas aeruginosa
  - c. Eikinella corrodans
  - d. Hemophilus influenzae
- 12. Dispose of used plates in biohazard container.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to apply the principle of microbial nutrition and metabolism, recognize the quality and characteristics of selective media and detail the principles of sterile technique and isolation.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate the isolation of a variety of five different cultures to include anaerobes, *Enterobacteriaceae*, gram positive bacilli, gram positive cocci, gram negative cocci and various miscellaneous gram negative bacteria.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets and Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: In preparing the workstation, the media appears caked and bumpy. Suggest a next course of action.



**MICROBIOLOGY** 

# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Set of specimens for a Gram stain

Crystal violet

Gram iodine

Decolorizer

Safranin 0 counter stain

3 x 1 inch glass microscope slides

Timer

Microscope

Control slides or control organisms

A procedure

Swabs

Gram stain reagents

OSHA-recommended personal protective equipment

Biohazard container

# **WORK TO BE PERFORMED**

Demonstrate the staining properties of bacteria representative of Gram positive and negative cocci and bacilli from original source cultures and from culture plates on which representative colonies have been isolated. Prepare, stain and interpret the slides. Record and report results.

# PERFORMANCE CRITERIA

Performance criteria include Gram staining and interpreting a variety of organisms to include representative *Enterobacteriaceae*, anaerobes, glucose nonfermenting Gram-negative bacilli, Gram-positive bacilli, Gram-positive cocci, Gram-negative cocci and other miscellaneous Gram-negative bacteria from a variety of potential body sites. Proficiency requires the 90% correct identification of 20 different unknown slides resembling clinical specimens and representing the various organisms and including the identification of red cells, differentiation of white cells, epithelial cells, yeast, bacteria, parasites and hyphal elements. Criteria for acceptable evaluation requires that the smear be one cell thick. Each slide may take 20 minutes to prepare, stain and evaluate. Time will vary.



# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Obtain swabs or smears directly from source or use prepared or stock cultures.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Work with live organisms under a biological safety hood.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble microscope slides, microscope with oil immersion lens and Gram stain reagents. Control slides for each type of Gram stain evaluation are required.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the specimen for acceptance or rejection for a Gram stain.

### Perform Procedure and Quality Control; Document and Evaluate:

5. Prepare the slide, one cell thick, and label the slide. Fix the specimen to the slide.

#### Stain:

- 6. Follow the procedure based on the manufacturer's directions and stain, decolorize and counterstain the smears.
- 7. Rinse and air dry.

#### Interpret:

8. Initially focus the microscope on low power then high power to locate the inoculum. Examine the stained smear under the oil immersion (100 x) objective.

#### Record, Evaluate and Report Results:

- 9. Interpret the control slides.
- 10. Record observations to include Gram-positive, Gram-negative or Gram-variable bacteria; size and shape of bacteria; arrangement of bacterial cells; and the presence or lack of specific structure organelles such as cellular elements and inclusions (spores, metachromatic granules, etc.) on the log sheet. Evaluate controls as a decision element in relationship to accepting and subsequent reporting of sample results. Report results or refer for review. Store slides.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

11. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test describing how the Gram stain differentiates the positive from the negative bacteria.

#### Demonstrate Procedure/Skill under Direct Observation:

Demonstrate stain procedure under direct observation to include accurate reading of the smear and recording and reporting of results. Requires 100% compliance with performance elements.



Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets and Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

### Demonstrate Problem-Solving Skills:

Example: The Gram-positive control appears pink under the microscope. List possible sources of error. Suggest a corrective course of action.



**MICROBIOLOGY** 

# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Five unknown organisms grown of 5% sheep blood agar

Positive and negative control

Hydrogen peroxide

Glass slide

A procedure

Wooden applicator sticks

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate the catalase test to differentiate *Staphylococci* from *Streptococci* or *Listeria* from *Streptococci*).

### PERFORMANCE CRITERIA

A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens and a positive and negative control. The tests will be completed and interpreted in five minutes.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble and Maintain Reagents and Controls:

Assemble hydrogen peroxide, controls, wooden applicator sticks and a glass slide.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

3. The test requires sufficient colony growth so that a portion of the colony may be moved from the culture plate to the glass slide.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 4. Transfer a portion of the colonies to a separate spot on the glass slides making sure not to include any agar (red blood cells are catalase positive).
- 5. Add the hydrogen peroxide to each of the five unknowns and to the positive and negative controls.



#### Record, Evaluate and Report Results:

- 6. Observe each colony for bubbles; record the activity.
- 7. Evaluate controls and, if accepted, report results.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Dispose of culture materials as an infectious waste. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the principle of the catalase test to differentiate Staphylococci and Micrococci species from other Aerobic Gram-Positive Cocci (i.e., Staphylococci from Streptococci or Listeria from Streptococci).

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

The criteria for acceptable performance follow published industry standards.

Complete Documentation of Worksheets and Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Both the positive and negative controls demonstrate no or a few bubbles that dissipate rapidly when the hydrogen peroxide is added. None of the five unknowns display any bubbles. Suggest an explanation and, if appropriate, suggest a corrective course of action.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Three unknown Staphylococci species grown of 5% sheep blood agar Positive and negative control

Rabbit plasma

Glass slides or tubes

Aprocedure

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate the coagulase test to speciate Staphylococcus aureus.

## PERFORMANCE CRITERIA

A minimum of three challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens with a positive and negative control. The tests will be completed and interpreted in five minutes.

Note: The tube test takes a minimum of 4 to a maximum of 24 hours to read.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble and Maintain Reagents and Controls:

2. Assemble rabbit plasma, controls, glass slides and/or tubes.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

3. The test requires sufficient colony growth so that a portion of the colony may be moved from the culture plate to the glass slide.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 4. Prepare a suspension of the suspected organism.
- Mix with a drop of rabbit plasma for the slide test and .5 mL for the tube test.

#### Record, Evaluate and Report Results:

- 6. Observe the slide for clumping or the tube for clotting (4 to 24 hours).
- 7. Evaluate controls (Staphylococcus aureus ATCC 25923 and Staphylococcus epidermidis ATCC 12228) and, if accepted, report results.



# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Dispose of culture materials as an infectious waste. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the clumping principle of the coagulase test including the difference between the slide (bound coagulase) and the tube (bound and free coagulase) test.

### Demonstrate Procedure/Skill under Direct Observation:

Demonstration requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

The criteria for acceptable performance follow published industry standards.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Both the positive and negative controls demonstrate no coagulation. None of the five unknowns show any sign of a fibrin clot. Suggest an explanation and, if appropriate, suggest a corrective course of action.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Three unknowns including representatives of the *Enterobacteriaceae* species grown of 5% sheep blood agar

Positive (Pseudomonas aeruginosa ATCC 27853) and negative control (Escherichia coli ATCC 25922)

Filter paper saturated with the substrate paraphenylenediamine dihydrochloride

A procedure

Glass slides

**Tubes** 

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate the oxidase spot test to assist in the identification of Enterobacteriaceae, Neisseria, Aeromonas, Vibrio and Campylobacter.

## PERFORMANCE CRITERIA

A minimum of three challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens with a positive and negative control. The tests will be completed and interpreted in five minutes.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble and Maintain Reagents and Controls:

2. Assemble filter paper containing the substrate paraphenylenediamine dihydrochloride, controls, glass slides and/or tubes and three unknowns.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

3. The test requires sufficient colony growth so that a portion of the colony may be moved from the culture plate to the filter paper.

#### Perform Procedure and Quality Control; Document and Evaluate:

4. Place colonies of the microorganism to be tested on the substrate-saturated filter paper.



### Record, Evaluate and Report Results:

- 5. Observe each colony for color change and record the activity.
- 6. Evaluate controls and, if accepted, report results.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Dispose of culture materials as an infectious waste. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the cytochrome C principle of the oxidase test in differentiating nonfermentors. Include in the discussion the role of NADH, the substrate paraphenylenediamine dihydrochloride and indophenol blue.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

The criteria for acceptable performance follow published industry standards.

Complete Documentation of Worksheets and Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The positive control demonstrates no color change. Interpret and suggest a corrective action as appropriate.



# SKILL STANDARD

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Three unknowns which are representatives of the *Enterobacteriaceae* species grown on MacConkey's agar

Positive and negative control

ONPG medium

A procedure

Culture plate

Incubator

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate the ONPG to indicate if the *Enterobacteriaceae* is a true lactose fermentor or not.

# **PERFORMANCE CRITERIA**

A minimum of three challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens with a positive and negative control. The tests will be completed and interpreted in five minutes.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble and Maintain Reagents and Controls:

2. Assemble ONPG reagent, controls and three unknowns.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

3. The test requires sufficient colony growth so that a portion of the colony may be moved from the culture plate to the test medium.

#### Perform Procedure and Quality Control; Document and Evaluate:

4. Place colonies of the microorganisms to be tested in the ONPG medium. Incubate for four hours.

#### Record, Evaluate and Report Results:

- 5. Observe each colony for color change and record the activity.
- 6. Evaluate controls and, if accepted, report results.



# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Dispose of culture materials as an infectious waste. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the principle of the o-nitrophenyl-beta-D-galactopyranoside (ONPG) test in relationship to the presence of beta-galactosidase and lactose fermentation.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

The criteria for acceptable performance follow published industry standards.

Complete Documentation of Worksheets and Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The positive control demonstrates no color change. Interpret and suggest a corrective action as appropriate.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Three unknown organisms grown on 5% sheep's blood agar

Positive and negative control

Bacitracin discs

A procedure

Inoculated surface

Incubator

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate the use of bacitracin susceptibility for the presumptive identification of *Streptococcus pyogenes* from other beta hemolytic groups.

### PERFORMANCE CRITERIA

A minimum of three challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens with a positive and negative control. The tests will be completed and interpreted in the course of 18 to 24 hours.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

1. Wash hands and put on gloves and other personal protective equipment.

#### Assemble and Maintain Reagents and Controls:

2. Assemble three suspected isolates of *Streptococcus pyogenes* (Group A), a positive and negative control, 5% sheep's blood agar and bacitracin disks (0.04 U).

#### Evaluate Sample/Specimen for Acceptability or Rejection:

3. The test requires a pure culture.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 4. Streak surface of agar plate to obtain confluent growth.
- 5. Aseptically place bacitracin disk onto inoculated surface. Press down gently on the disk to ensure complete contact with the agar surface.
- 6. Invert and incubate at 35° Centigrade for 18 to 24 hours.



#### Record, Evaluate and Report Results:

- 7. Any zone of inhibition of growth from a beta hemolytic isolate surrounding the bacitracin disk is indicative of a presumptive Group A streptococci. Most other beta hemolytic streptococci grow to the edge of the disk and produce no zone of inhibition.
- 8. The positive control: Group A streptococcus. The negative control: Group B streptococcus.
- 9. Evaluate controls and, if accepted, report results.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

10. Dispose of culture materials as an infectious waste. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the principle that Group A streptococci are susceptible to low levels (0.04 U) of bacitracin whereas other groups are resistant. Explain the significance of applying this test only to pure cultures.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

The criteria for acceptable performance follow published industry standards.

Complete Documentation of Worksheets and Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Both the positive and negative control, as well as all three unknowns, demonstrate susceptibility to the isolates. Evaluate and, if appropriate, suggest a corrective action.



#### MICROBIOLOGY

# **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Throat swab labeled to include patient identification, source of specimen, antibiotic therapy (if any) and date and time of collection; note if any antibiotics have been taken within the previous two weeks

Sheep blood agar

Bacitracin disc

35° Centigrade incubator

Refrigerator

Microscope with an oil immersion lens

Negative (ATCC 13813)

Positive (ATCC 19615) controls

Incinerator

Inoculating loops

OSHA-recommended personal protective equipment

Biohazard container

# **WORK TO BE PERFORMED**

Isolate and identify pathogens from a throat culture.

# PERFORMANCE CRITERIA

Accurate identification of Group A strep requires the ability to identify hemolysis and to differentiate beta from alpha hemolysis on sheep blood agar.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Refer to protocol for collecting throat cultures in Test Management.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble materials to include sheep blood agar, bacitracin discs (or special media developed to screen specifically for Group A streptococci), incubator maintained at 35° Centigrade, refrigerator in which to keep agar and reagents monitored to maintain between 2-8° Centigrade, microscope with an oil immersion lens, surface disinfectant, incinerator, inoculating loops and biohazard containers.



### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Properly labeled specimens from which time of collection to time to culture does not exceed the limits established by the laboratory.

## Perform Procedure and Quality Control; Document and Evaluate:

- 5. Given a throat specimen, roll the swab gently on the surface of one quadrant of a labeled and dated blood agar plate.
- 6. Sterilize the loop. Using the "streak to stab" technique, inoculate the sheep's blood agar plate in four consecutive quadrants ending with the fishtail for isolation.
- 7. Incubate aerobically or anaerobically for 18 to 24 hours If beta hemolysis is evident, move to presumptive identification.

#### Presumptive Identification:

- 8. Select a single beta hemolytic colony from the primary plate; create a confluent field of inoculum on the secondary sheep blood agar plate. Prepare gram stain to confirm.
- 9. Aseptically place a bacitracin disc in the center of the inoculated section. Incubate aerobically overnight.

#### Record, Evaluate and Report Results:

10. A negative is the absence of beta hemolytic colonies on the blood agar plate. This should be reported as "No Group A Streptococcus isolated." A presumptive positive is any zone of growth inhibition around the 0.04 unit bacitracin disk. This is demonstrated by seeing any intact red cells around the disk. This finding should be reported as "Presumptive Group A Streptococcus by bacitracin." Beta hemolytic streptococcus-like colonies with no zone of inhibition around the bacitracin disk are reported as "Negative for Group A Streptococcus" or "Beta hemolytic streptococci not Group A by bacitracin."

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

11. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

# Complete Documentation of Worksheets and Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The problem-solving task is related directly to the successful performance of the skill and is designed to demonstrate the applied, analytical, assessing and evaluative skill of the challenger. Suggest a course of corrective action.



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**IMMUNOLOGY** 

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Three serum samples

Positive and negative controls

Slides

Reagents including horse erythrocytes and guinea pig antigen

Stop watch

Rapid slide test performed to detect infectious mononucleosis

OSHA-recommended personal protective equipment

Biohazard container

Serum dispensers

Stirrers

Capillary pipette

Disposable plastic pipette

Applicator sticks

Indicator sticks

## **WORK TO BE PERFORMED**

Assess suitability of specimen and reagents. Following step-by-step procedure, perform test on accepted sample and controls. Interpret and report results.

## **PERFORMANCE CRITERIA**

Test will be performed with 100% accuracy in five minutes or less.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Collect a sample from client by venipuncture. Centrifuge to retrieve serum.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble equipment and materials (gloves; hand disinfectant; test serum; stop watch; surface disinfectant; kit to include instructions, slide, serum dispensers, stirrers and reagents; and biohazard container).

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Compare the serum sample with the collection, handling and transport criteria. Accept or reject.



## Perform Procedure and Quality Control; Document and Evaluate:

- 5. Place the slide on a flat work surface. Mix the reagent vials several times by inversion.
- 6. Fill the capillary pipette to the top mark.
- 7. Deliver the remaining cells (10 uL) to a corner of square 2.
- 8. Mix sera with the guinea pig antigen.
- 9. Place one drop of thoroughly mixed reagent 2 in the corner of square 2.
- Add one drop of serum to the center of each square using the disposable plastic pipette provided.
- 11. Use a clean applicator stick to mix reagent 1 with the serum using at least ten stirring motions while not touching the indicator cells.
- 12. Blend the indicator cells in square 1 with the applicator stick using no more than ten stirring motions. Spread the mixture over the entire surface of the square.
- 13. Repeat steps 11 and 12 using reagent 2 in square 2 and using a clean indicator stick.
- 14. Start the stop watch after mixing both squares.
- 15. Observe for agglutination at the end of one minute without moving or picking up the slide.

#### Record, Evaluate and Report Results:

16. Record the agglutination in each square. Include the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. If the agglutination pattern is stronger in square 1 with the serum sample absorbed with guinea pig antigen plus horse erythrocytes than in square 2 with horse erythrocytes alone, the test is positive for the heterophile antibody of infectious mononucleosis. Any other combination of reactions is negative.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

17. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test of the principle of serological procedure to detect heterophile antibodies, the relationship of test results to the disease and the relationship of the presence of heterophile antibodies with other possible hematologic findings.

## Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.



Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: When mixed with the horse erythrocyte indicator cells, the serum sample absorbed with guinea pig antigen yields the same degree of agglutination as does the serum and horse erythrocytes without absorption of the antigen. The controls worked. Interpret these results.



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Series of five unknowns and a positive and negative control

Test tubes

**Pipettes** 

Incubators or refrigerators

A specific procedure

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Demonstrate a titration such as an antistreptolysin O or cold agglutinin.

## PERFORMANCE CRITERIA

The challenge must provide for a minimum of five samples that cover the full range of reactivity from highly reactive to nonreactive. The criteria for acceptable performance requires that the unknown values meet the target value  $\pm 2$  dilutions or positive or negative to match the referee. Depending on the procedure demonstrated, the time may vary.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Unknown serum samples may be previously prepared. If specimens are to be collected, take into consideration special requirements such as those for cold agglutinins.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. The different titration procedures will require slightly different equipment and may require preparation of special reagents.

## Evaluate Sample/Specimen for Acceptability or Rejection:

4. Note any hemolysis or lipemia that may interfere with determining end points.

#### Perform Procedure and Quality Control; Document and Evaluate:

5. Perform the select test with the unknowns and controls provided.



#### Record, Evaluate and Report Results:

6. Read the end point in the titrations. Record results and calculate titer in each tube.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The positive control showed no change. Suggest a corrective course of action.



**IMMUNOLOGY** 

## SKILL STANDARD

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Series of five unknowns

Positive and negative control

Test tubes

**Pipettes** 

Incubators or refrigerators

A specific procedure

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Demonstrate a neutralization assay such as an Anti-DNASE.

## **PERFORMANCE CRITERIA**

The challenge must provide for a minimum of five samples that cover the full range of reactivity from highly reactive to nonreactive. The criteria for acceptable performance requires that the unknown values meet the target value  $\pm 2$  dilutions or positive or negative to match the referee. Depending on the procedure demonstrated, the time may vary.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Unknown serum samples may be previously prepared. If specimens are to be collected, take into consideration any special requirements.

## Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. The different titration procedures will require slightly different equipment and may require preparation of special reagents.

## Evaluate Sample/Specimen for Acceptability or Rejection:

4. Note any hemolysis or lipemia that may interfere with determining end points.

## Perform Procedure and Quality Control; Document and Evaluate:

5. Perform the select test with the unknowns and controls provided.



#### Record, Evaluate and Report Results:

6. Read the end point, record results and calculate titer in each tube.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The positive control showed no change. Suggest a corrective course of action.



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## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Series of five unknowns and a positive and negative control

Test tubes

**Pipettes** 

Incubators or refrigerators

A specific procedure

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Demonstrate a ligand assay.

## **PERFORMANCE CRITERIA**

The challenge must provide for a minimum of five samples that cover the full range of reactivity from highly reactive to nonreactive. The criteria for acceptable performance requires that the unknown values meet the target value  $\pm 2$  dilutions or positive or negative to match the referee. Depending on the procedure demonstrated, the time may vary.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Unknown serum samples may be previously prepared. If specimens are to be collected, take into consideration special requirements.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. The different titration procedures will require slightly different equipment and may require preparation of special reagents.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Note any hemolysis or lipemia that may interfere with determining end points.

#### Perform Procedure and Quality Control; Document and Evaluate:

5. Perform the selected test with the unknowns and controls provided.



#### Record, Evaluate and Report Results:

6. Read the end point, record results and calculate titer in each tube.

Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The positive control showed no change. Suggest a corrective course of action.



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## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Series of five unknowns and a positive and negative control

Test tubes

**Pipettes** 

Fluorescent microsope

A specific procedure

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Demonstrate an immunofluorescence assay such as an antinuclear antibody or a fluorescent treponenal antibody absorption.

## PERFORMANCE CRITERIA

The challenge must provide for a minimum of five samples that cover the full range of reactivity from highly reactive to nonreactive. The criteria for acceptable performance requires that results match the referee in recognizing and grading fluorescence patterns such as speckled, nucleolar, peripheral, homogenous, centroonmeere and treponemes. Depending on the procedure demonstrated, the time may vary.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Unknown serum samples may be previously prepared. If specimens are to be collected, take into consideration special requirements.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. The different titration procedures will require slightly different equipment and may require preparation of special reagents.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Note any hemolysis or lipemia that may interfere with determining end points.



## Perform Procedure and Quality Control; Document and Evaluate:

5. Perform the select test with the unknowns and controls provided.

#### Record, Evaluate and Report Results:

6. Read the end point, record results and calculate titer in each tube.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The positive control showed no change. Suggest a corrective course of action.



**IMMUNOLOGY** 

## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Series of five unknowns and a positive and negative control

Test tubes

**Pipettes** 

Incubators or refrigerators

A specific procedure

Slide

Rheumatoid factor reagents

Stop watch

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Demonstrate an agglutination assay such as any latex, red cell or bacterial typing. For example, perform a rapid slide test to aid in distinguishing rheumatoid arthritis from other causes of arthritis.

## **PERFORMANCE CRITERIA**

The challenge must provide for a minimum of five samples that cover the full range of reactivity from highly reactive to nonreactive. The criteria for acceptable performance requires that the unknown values meet the target value ±2 dilutions or positive or negative to match the referee. Depending on the procedure demonstrated, the time may vary.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Unknown serum samples may be previously prepared. If specimens are to be collected, take into consideration special requirements such as those for cold agglutinins.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. The different titration procedures will require slightly different equipment and may require preparation of special reagents.



#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Note any hemolysis or lipemia that may interfere with determining end points.

# Perform Procedure and Quality Control; Document and Evaluate: (Follow manufacturer's instructions)

- 5. Assemble equipment and materials (gloves; hand disinfectant; test serum; stop watch; surface disinfectant; kit to include RF latex reagent, RF positive and negative controls, glycine diluent and slide; biohazard container; and applicator sticks, if not provided).
- 6. Allow reagents to reach room temperature before performing test.
- 7. Prepare 1:20 dilution of test serum.
  - a. Pipette 0.05 mL of serum into 13 x 75 mm tube.
  - b. Pipette 0.95 mL of glycine diluent into the tube and mix well.
- 8. Dispense one drop of positive control serum into ring on slide.
- 9. Dispense one drop of negative control serum into second ring on slide.
- 10. Dispense one drop of diluted patient serum into third ring on slide using dispenser spreader provided.
- 11. Mix the rheumatoid factor latex reagent well by inversion.
- 12. Dispense one drop of well-mixed rheumatoid factor latex reagent into each of the three rings containing controls or diluted serum.
- 13. Using a separate spreader or applicator stick for each control and serum, thoroughly mix control or serum with the latex reagent spreading the mixture over the entire surface of the ring.
- 14. Rock the slide in a figure-eight motion for the appropriate time (two to three minutes) to continue mixing.
- 15. Observe the rings for agglutination immediately at the end of the appropriate time period.

#### Record Control and Patient Results:

16. Record results of the controls and patient serum (+ = agglutination, 0 = no agglutination).

#### Interpret Results:

17. If the controls worked and the patient serum is positive, proceed to perform the quantitative test.

#### Quantitative Test:

- 18. Prepare a two-fold serial dilution of patient serum.
  - a. Label five test tubes: 1(1:40), 2(1:80), 3(1:160), 4(1:320) and 5(1:640).
  - b. Pipette 0.5 mL of glycine diluent into each tube.
  - c. Pipette 0.5 mL of 1:20 dilution of patient serum (from qualitative test or step 8) into tube 1(1:40) and mix contents of tube well.
  - d. Transfer 0.5 mL from tube 1 to tube 2 and mix well.
  - e. Transfer 0.5 mL from tube 2 to tube 3 and mix well.
  - f. Transfer 0.5 mL from tube 3 to tube 4 and mix well.
  - g. Transfer 0.5 mL from tube 4 to tube 5 and mix well.
- 19. Use each dilution (tubes 1-5) as a separate test specimen and perform the agglutination test as in steps 9 through 17.

#### Record, Evaluate and Report Results:

20. Record the results for each tube. Record the serum Rheumatoid Factor titer (the reciprocal of the highest dilution that shows agglutination).

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

21. Clean work area with disinfectant. Remove gloves and discard. Wash hands.



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# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

## Demonstrate Problem-Solving Skills:

Example: The positive control showed no change. Suggest a corrective course of action.



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Series of five unknowns Positive and negative control Test tubes

Pipettes

Incubators or refrigerators

A specific procedure

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Demonstrate a flocculation test such as a VDRL or the Rapid Plasma Reagin (RPR) test for Syphilis.

## **PERFORMANCE CRITERIA**

The challenge must provide for a minimum of five samples that cover the full range of reactivity from highly reactive to nonreactive. The criteria for acceptable performance requires that the unknown values meet the target value  $\pm 2$  dilutions or positive or negative to match the referee. Depending on the procedure demonstrated, the time may vary.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Unknown serum samples may be previously prepared. If specimens are to be collected, take into consideration special requirements such as those for cold agglutinins.

# Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. The different titration procedures will require slightly different equipment and may require preparation of special reagents.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Note any hemolysis or lipemia that may interfere with determining end points.



## Perform Procedure and Quality Control; Document and Evaluate:

5. Perform the select test with the unknowns and controls provided. The equipment, glassware, reagents, controls and techniques must conform to manufacturer's specification. Each test run must include a positive serum control of known titer or controls of graded reactivity plus a negative control.

#### Record, Evaluate and Report Results:

6. Interpret reactivity of unknowns and record results.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to relate syphilis with sexually transmitted diseases, the contraction and progression of the disease, the principle of the VDRL and RPR and procedures for confirming a reactive syphilis screening test.

## Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The positive control showed no change. Suggest a corrective course of action.



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Series of five unknowns
Positive and negative control
Test tubes
Pipettes
Immunophoresis apparatus
A specific procedure
OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Biohazard container

Demonstrate an electrophoretic pattern such as hemoglobin.

## **PERFORMANCE CRITERIA**

The challenge must provide for a minimum of five samples that cover the full range of reactivity from highly reactive to nonreactive. The criteria for acceptable performance requires that the unknown values meet the target value  $\pm 2$  dilutions or positive or negative to match the referee. Depending on the procedure demonstrated, the time may vary.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Unknown serum samples may be previously prepared. If specimens are to be collected, take into consideration special requirements such as those for hemoglobin electrophoresis.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. The different titration procedures will require slightly different equipment and may require preparation of special reagents.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Note any hemolysis or lipemia that may interfere with determining end points.



#### Perform Procedure and Quality Control; Document and Evaluate:

5. Perform the selected test with the unknowns and controls provided.

#### Record, Evaluate and Report Results:

6. Read and interpret results. Measure peak migration, if applicable. Prepare standard curve. Calculate concentration of unknown from curve.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

## Demonstrate Problem-Solving Skills:

Example: The positive control showed no change. Suggest a corrective course of action.



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

## Given the following:

Series of five unknowns

Standards and positive controls with specified concentrations

Negative control

Test tubes

**Pipettes** 

Incubators or refrigerators

A specific procedure

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Demonstrate a radial immunodiffusion for the semiquantification of a variety of antigen-antibody combinations such as immunoglobulins or apolipoproteins.

## PERFORMANCE CRITERIA

The challenge must provide for a minimum of five samples that cover the full range of reactivity from highly reactive to nonreactive. The criteria for acceptable performance requires that the unknown values meet the target value  $\pm 2$  dilutions or positive or negative to match the referee. Depending on the procedure demonstrated, the time may vary.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Unknown serum samples may be previously prepared. If specimens are to be collected, take into consideration special requirements.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment. Ensure availability of biohazard containers and surface disinfectants.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. The different radial immunodiffusion procedures may require slightly different equipment and the preparation of special reagents and gels.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Note any hemolysis or lipemia that may interfere with determining end points.



#### Perform Procedure and Quality Control; Document and Evaluate:

5. Perform the select test with the unknowns and controls provided.

#### Record, Evaluate and Report Results:

6. Measure the diameter of the precipitin rings. Plot a concentration gradient or calculate or verify the standard curve. Determine the concentration of the unknown from the curve.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

7. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to describe the principles of radial immunnodiffusion (passive diffusion) and factors interfering with these assays.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

## Demonstrate Problem-Solving Skills:

Example: The standard curve is nonlinear. Suggest a corrective course of action.



# **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Prospective donor candidate

Scales

Thermometer or other devices

Blood pressure monitoring equipment

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Gather information and compare to requirement criteria to accept or reject.

## PERFORMANCE CRITERIA

Criteria for acceptable performance is 100%. A minimum of five challenge candidates is needed to demonstrate a full range of potentially acceptable and unacceptable donors.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Inform client of expected procedures.

## Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment for examination phase as required.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble scales, thermometer or other devices and blood pressure monitoring equipment.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 4. Identify the prospective donor, review previous donation records and record donor's medical donation history.
- 5. Perform physical examination to include weight, temperature, pulse and blood pressure. Evaluate in relationship to acceptable criteria.
- 6. Determine and evaluate hemoglobin and hematocrit in relationship to acceptable criteria.
- 7. If donor is accepted, obtain informed consent of prospective donor.
- 8. Discuss disease transmission and confidential exclusion with prospective donor.
- 9. Refer unusual circumstances to technical supervisor or medical director.



#### Record, Evaluate and Report Results:

10. Maintain donation records.

Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

11. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on written test to identify criteria for accepting and rejecting prospective donors.

## Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The prospective donor is a female with a hemoglobin of 9.0 mg/dL. Suggest an appropriate course of action.



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Properly completed request

Blood specimens from clearly and carefully identified potential recipients

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

Donor units

Needles

Surgical antiseptic

Properly labeled container

Anticoagulant

OSHA-recommended personal protective equipment

Biohazard container

## **WORK TO BE PERFORMED**

Collect single unit of blood from donor.

## PERFORMANCE CRITERIA

Criteria for acceptable performance is 100%. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity from abnormal low, expected to abnormal high ranges.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Donor may be real or simulated. If collection is required for potential client transfusion, follow the facility protocol and procedures for uniquely identifying the recipient.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble donor units, needles and surgical antiseptic.

## Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assure that donors and units are uniquely identified.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Verify the identity of the donor. Complete health-related checks such as hematocrit and blood pressure. Accept or reject donor based on criteria.
- 6. Using properly labeled container and anticoagulant, surgically prepare arm for phlebotomy using aseptic technique. Complete venipuncture.
- 7. Observe for adverse donor reactions to phlebotomy to include alertness, blood pressure, color, etc.
- 8. Maintain product sterility.

#### Record, Evaluate and Report Results:

9. Complete and maintain donor records.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

10. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on donor requirements.

## Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

## Demonstrate Problem-Solving Skills:

Example: The donor states that he/she feels faint during the collection procedure. Suggest a corrective course of action.



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## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Selection of donors, real or simulated
Supervision of a technical supervisor or laboratory director
Facility-specific protocol and related procedures
Donor blood
OSHA-recommended personal protective equipment
Biohazard container

## **WORK TO BE PERFORMED**

Process donor blood.

## **PERFORMANCE CRITERIA**

Criteria for acceptable performance is 100%. A minimum of five challenge samples must demonstrate a full range of samples that describes results expected in unknown specimens including a full range of reactivity from abnormal low, expected to abnormal high ranges.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Donors may be real or simulated. If collection is required for potential client transfusion, follow the facility protocol and procedures for uniquely identifying the recipient.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble donor blood and identify testing facilities.

## Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assure that donors are uniquely identified.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Perform ABO and Rh typing on the donor units.
- 6. Either perform or send for testing for the following communicable diseases or viruses: hepatitis B and C, syphilis, cytomegalovirus, HIV and HTLV, ALT and antibody screen.
- 7. Label products.
- 8. Store products according to specifications.



#### Record, Evaluate and Report Results:

9. Maintain records of donor products.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

10. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on written test of donor requirements.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The donor presents as weak D positive. How is the unit labeled with respect to Rh?



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Properly completed request

Blood products

Appropriate equipment

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

Centrifuge

Plasma expresser

Automatic cell washer

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Harvest components from single-donor units.

## PERFORMANCE CRITERIA

Criteria for acceptable performance is 100%. Demonstrate the processing/ harvesting of a minimum of five challenge/simulated donor units representing a range of various products and decision criteria for accepting or rejecting the donor products.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Blood products or simulations may be provided. If collection is required, follow the facility-specific protocol.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

## Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Calibrate and balance centrifuge.

## Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assure that specimens are uniquely identified.

## Perform Procedure and Quality Control; Document and Evaluate:

- 5. Centrifuge units of whole blood.
- 6. Prepare packed red blood cells using a plasma expresser.
- 7. Prepare washed red blood cells using automatic cell washer.



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- 8. Prepare leukocyte-depleted red blood cells by automated washing, filtration or freezing and deglycerolizing.
- 9. Prepare platelet concentrates by centrifugation and separation.
- 10. Irradiate red blood cells or platelet concentrates as required.
- 11. Prepare fresh frozen plasma.
- 12. Prepare single-donor plasma.
- 13. Prepare cryoprecipitate.
- 14. Properly label components including name of product, expiration dates, etc.
- 15. Properly store components.
- 16. Monitor storage equipment and maintain storage equipment records.
- 17. Maintain quality assurance program.
- 18. Package and ship products including preparing transfer records, determining appropriate shipping conditions and maintaining current inventory.

#### Record, Evaluate and Report Results:

19. Maintain appropriate records pertaining to donor identification, test results, etc. Report any unexpected or unusual findings to technical supervisor or laboratory director.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

20. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better.

## Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The donor unit for component harvesting has set out at room temperature for four hours. Evaluate suitability of unit for continuing the harvesting process. Detail an appropriate course of action.



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Properly completed request

Blood specimens from clearly and carefully identified clients

Controls

Typing antisera

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

**Pipettes** 

Clean microscope slides

Wax pencil

Applicator sticks

Light source

Blood grouping worksheet

Timing device

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Perform antigen typing ABO by Rapid Slide Test.

## PERFORMANCE CRITERIA

Criteria for acceptable performance is 100%. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Cell and sera samples may be provided. If collection is required for potential client transfusion, follow the facility protocol and procedures for uniquely identifying the recipient.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble blood and antisera, pipettes, clean microscope slides, wax pencil, applicator sticks, light source, blood grouping worksheet and timing device.



#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assure that specimens are uniquely identified.

## Perform Procedure and Quality Control; Document and Evaluate:

- 5. Place a clean slide on the work area.
- 6. Mark the slide into two halves using a wax pencil and label.
- 7. Place the antisera on the marked, designated areas.
- 8. Add one drop of well-mixed sample and mix.
- 9. Rock gently for two minutes and look for agglutination using strong light.

#### Record, Evaluate and Report Results:

10. Record results on worksheet. Interpret results.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

11. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on written test to explain the ABO system and mechanism by which the typings work.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Interpret the following results:

	Anti-A	Anti-B
Sample 1	+	0
2 0	+	
3	0	0
4	+	+



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## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Properly completed request

Blood specimens from clearly and carefully identified clients

Controls

Typing antisera

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

Reagent cells

**Pipettes** 

Clean microscope slides

Wax pencil

Applicator sticks

Serofuge

Blood grouping worksheet

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Perform ABO typing by Rapid Tube Test.

## PERFORMANCE CRITERIA

Criteria for acceptable performance is 100%. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Cell and sera samples may be provided. If collection is required for potential client transfusion, follow the facility protocol and procedures for uniquely identifying the recipient.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble a 5% suspension of red blood cells and antisera, reagent cells, pipettes, clean microscope slides, wax pencil, applicator sticks, serofuge to spin at 2000-2500 rpm and blood grouping worksheet.



## Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assure that specimens are uniquely identified.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Centrifuge blood sample; remove serum from sample; and place in a clean, labeled test tube.
- 6. Prepare a 5% suspension of patient red cells in a clean tube labeled with patient name. Place one drop of well-mixed blood into a test tube. Add eighteen to nineteen drops of saline.
- 7. Label five test tubes for each sample: Anti-A, Anti-B, A cells, B cells and, if required as part of the procedure, an auto control.
- 8. Place one drop of the antisera into the correctly labeled tubes.
- 9. Place one drop of the 5% patient cell suspension in the tubes marked Anti-A, Anti-B and, if performed as part of the required procedure, an auto control.
- 10. Place two drops of patient serum into each of the tubes marked A, B and, if required as a part of the procedure, an auto control.
- 11. Place tubes in the serofuge and spin for 30 seconds.
- 12. Allow serofuge to come to a complete stop before removing tubes.

#### Record, Evaluate and Report Results:

- 13. Tap each tube gently to loosen cells from bottom of tube and observe cells for agglutination using good light.
- 14. Record results from each tube on worksheet.
- 15. Interpret results to determine the blood group of the samples and record.
- 16. If the auto control is negative and the forward and reverse typing patterns agree, report results.
- 17. Report ABO discrepancies to the technical supervisor or laboratory director. As requested, perform tests to resolve ABO discrepancies.
  - a. Perform and interpret tests using lectins.
  - b. Perform and interpret saline replacement techniques.
  - c. Perform reverse grouping with A1, A2 and O cord cells and interpret test results.
  - d. Perform ABO typing on washed red cells.
  - e. Analyze patient diagnosis and transfusion history for explanations of discrepancies.
  - f. Correlate laboratory results consistent with the possible discrepant groups.
    - (1) Subgroups of A and B
    - (2) Newborns
    - (3) Transfusion resulting in a mixed cell population
    - (4) Missing antibodies in newborns, elderly or immunodeficient patients
    - (5) Unexpected antibodies
    - (6) Autoantibodies
    - (7) Rouleaux

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

18. Clean work area with disinfectant. Remove gloves and discard. Wash hands.



## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the ABO system and mechanism by which the typings work.

## Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Interpret the following results and suggest a corrective course of action, if required:

	Anti A	Anti B	AC	BC
Patient Results	4+	0	1+	0



## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Properly completed request

Blood specimens from clearly and carefully identified clients

Controls

Typing antisera

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

**Pipettes** 

Clean microscope slides

Wax pencil

Applicator sticks

Light source

Blood grouping worksheet

Timing device

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Perform antigen typing for Rh including test for weak D antigen.

## PERFORMANCE CRITERIA

Criteria for acceptable performance is 100%. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of expected reactivity from abnormal low to abnormal high ranges.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Cell and sera samples may be provided. If collection is required for potential client transfusion, follow the facility protocol and procedures for uniquely identifying the recipient.

## Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

 Assemble blood and antisera, pipettes, clean microscope slides, wax pencil, applicator sticks, light source, blood grouping worksheet and timing device.



#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assure that specimens are uniquely identified.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Perform and interpret Rh (D) typing by slide.
- 6. Perform and interpret Rh (D) typing by tube.
  - a. High protein reagent with Rh control
  - b. Saline reactive IgM reagent
  - c. Chemically modified
  - d. Micro titer
- 7. Perform and interpret Weak D typing.
  - a. Macroscopic
  - b. Microscopic
- 8. Perform and interpret quality control procedures for Rh.

#### Record, Evaluate and Report Results:

9. Record results on worksheet. Interpret results. Report discrepancies and unusual results to technical supervisor or laboratory director.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

10. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on written test to explain the Rh (D) system and mechanism by which the typings work.

## Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Interpret the following results:

Reactions of Cells with				
	Anti-D Antihuman globulin phase	Control Serum Antihuman globulin phase		
Sample 1	+	0		
2	0	0		
3	+	+		



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## **SKILL STANDARD**

## **CONDITIONS OF PERFORMANCE**

#### Given the following:

Properly completed request

Blood specimens from clearly and carefully identified clients

Controls

Typing antisera

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

Pipettes

Clean tubes

Wax pencil

Applicator sticks

Light source

Blood grouping worksheet

Timing device

OSHA-recommended personal protective equipment

## **WORK TO BE PERFORMED**

Perform antigen typing for a sample of other antigens such as Kidd, Kell, Duffy, Lewis, etc.

## **PERFORMANCE CRITERIA**

Criteria for acceptable performance is 100%. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Cell and sera samples may be provided. If collection is required for potential client transfusion, follow the facility protocol and procedures for uniquely identifying the recipient.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble blood and antisera, pipettes, clean tubes, wax pencil, applicator sticks, light source, blood grouping worksheet and timing device.



#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assure that specimens are uniquely identified.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Perform specific antigen typings, both saline and antihuman globulin. Include a positive and negative control.
- 6. Perform and interpret antigen typing for an array of antigens other than ABO and Rh.
- 7. Perform quality control procedures for these antigens.

#### Record, Evaluate and Report Results:

8. Record results on worksheet. Interpret results. Report discrepancies and usual results to technical supervisor or laboratory director.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

9. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on written test to explain the various red cell antigen systems and the mechanisms by which the different saline and antihuman globulin typings work.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

## Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: When performing antigen typing, agglutination is 3+ in a sea of free cells. Records from previous transfusion history state that the patient has been transfused in the previous month. Interpret these results, and suggest an appropriate course of action.



## IMMUNOHEMATOLOGY AND TRANSFUSION MEDICINE

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Properly completed request

Blood specimens from clearly and carefully identified potential recipients

Screening and panel cells or appropriate reagents

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

Serofuges

Polyspecific antisera

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Perform an antibody screen and identification.

#### PERFORMANCE CRITERIA

Criteria for acceptable performance is 100%. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including the presence and absence of immune/irregular antibodies.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Cell and sera samples may be provided. If collection is required for potential client transfusion, follow the facility protocol and procedures for uniquely identifying the recipient.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagent blood cells and sera, serofuges and polyspecific antisera.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assure that specimens are uniquely identified.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Perform and interpret antibody screening including antiglobulin phase test for a single atypical antibody.
- 6. Perform antibody identification panel test on serum or eluate and interpret the identity of the most probable antibody.



- 7. Confirm the antibody identification by
  - a. Antigen typing of patient cells and interpretation of results,
  - b. Devising a select cell panel of three antigen positive and three antigen negative cells.
- 8. Resolve complex antibody problems by performing the following:
  - a. Alteration of reaction conditions for antibody identification panel to include the use of appropriate controls and subsequent interpretation of results to include
    - (1) Increased serum volume;
    - (2) Use of enzymes;
    - (3) Use of enhancement media such as albumin, low ionic strength solutions, polyethylene glycol and polybrene;
    - (4) pH adjustment;
    - (5) Neutralization techniques;
    - (6) Reduced reaction temperatures;
    - (7) Prewarm technique;
    - (8) Saline replacement technique.
  - b. Antibody absorption, both autologous and heterologous.
  - c. Analysis of results for dosage effect.
  - d. Special antigen typings.
- 9. Interpret multiple antibody reaction patterns on a panel and refer to technical supervisor.
- 10. Differentiate clinically significant and insignificant antibodies.

#### Record, Evaluate and Report Results:

11. Report positive study results to the technical supervisor or laboratory director for interpretation, reporting and action.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

12. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to list antibodies of interest and to explain the principles behind antibody screening and identification.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Reactions were weak at room temperature and at the antihuman globulin phase with all panel cells. Suggest a next course of action.



## IMMUNOHEMATOLOGY AND TRANSFUSION MEDICINE

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Properly completed request

Blood specimens from clearly and carefully identified potential recipients

Required reagents

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

Donor blood cells

Serofuges

Typing sera and antisera

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Perform routine pretransfusion compatibility testing.

#### PERFORMANCE CRITERIA

Criteria for acceptable performance is 100%. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including ABO discrepancies and clinically significant and insignificant antibodies for the potential recipient.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Cell and sera samples may be provided. If collection is required for potential client transfusion, follow the facility protocol and procedures for uniquely identifying the recipient.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble donor blood cells, serofuges and typing sera and antisera.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Assure that specimens are uniquely identified.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Check records of previous transfusion for blood type and evidence of atypical antibodies or transfusion reactions.
- 6. Perform ABO group and Rh(D) typings and antibody screen.



- 7. Select ABO group and Rh type-specific or compatible blood.
- 8. Assess the extent of pretransfusion testing needed for each of the following possible scenarios:
  - a. type and hold,
  - b. type and screen,
  - c. routine transfusion,
  - d. emergency transfusion,
  - e. massive transfusion,
  - f. neonatal transfusion.
- 9. Perform the type and screen.
- 10. Perform the immediate spin abbreviated cross match to detect ABO incompatibility.
- 11. Perform routine antiglobulin cross match.
- 12. Release compatible units for transfusion.
- 13. Complete the appropriate records of released units.
- 14. Retain specimens from the recipient and donor for the appropriate length of time.
- 15. Perform tests used to resolve compatibility testing problems using the methods used to resolve antibody identification problems.
- 16. Select antigen negative blood for compatibility testing.
- 17. Correlate results which are consistent with the following causes of incompatible test results:
  - a. atypical antibodies,
  - b. rouleaux,
  - c. autoantibodies.
  - d. positive direct antihuman globulin tests on donor cells.
- 18. Apply appropriate labels and compatibility tags to selected donor units.

#### Record, Evaluate and Report Results:

19. Complete all records and report any significant findings to the technical supervisor or laboratory director.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

20. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the procedures and steps in compatibility testing and in resolving incompatible findings.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.



Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The cross match was incompatible in the antihuman globulin phase, but the antibody screen was negative. Evaluate and suggest a course of action.



# PERFORM AND INTERPRET DIRECT ANTIGLOBULIN TESTING; INVESTIGATE POSITIVE DIRECT ANTIGLOBULIN TEST DUE TO AUTOIMMUNE HEMOLYTIC ANEMIA.

## IMMUNOHEMATOLOGY AND TRANSFUSION MEDICINE

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Blood samples

Controls

Polyspecific and monospecific reagents

Completed request

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

Antihuman globulin reagent

Patient red blood cells

Test tubes

Serofuges

Timer

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Perform and interpret direct antiglobulin testing including the use of polyspecific and monospecific reagents.

#### PERFORMANCE CRITERIA

Criteria for acceptable performance is 100%. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity.

#### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Blood samples and various unknowns may be supplied.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble antihuman globulin reagent, patient red blood cells, test tubes, serofuges, timer and controls.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate serum for evidence of hemolysis or lipemia.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Perform the direct and antihuman globin test.
- 6. If positive, assess autocontrol and investigate to resolve the cause of these results in the following autoimmune hemolytic anemia conditions, hemolytic disease of the newborn and/or transfusion reactions.

#### Record, Evaluate and Report Results:

7. Report positive study results to the technical supervisor or laboratory director for interpretation, reporting and action.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the mechanism of the direct antihuman globulin test.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The direct antihuman globulin test (DAT) is positive in a sea of free cells. Suggest a reason and a course of further investigation as indicated.



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## IMMUNOHEMATOLOGY AND TRANSFUSION MEDICINE

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Unsensitized mother

Rh positive baby

Rh immune globulin

Tests to semiquantitate maternal/fetal bleed

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

Rh typing sera

Reagents

Test tubes

Calibrated serofuge

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Perform routine testing for the administration of Rh immune globulin.

#### PERFORMANCE CRITERIA

Criteria for acceptable performance is 100% compliance. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity.

#### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Testing requires cord blood and maternal samples.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble Rh typing sera, reagents for Kleihauer-Betke acid elution to quantitate the transplacental hemorrhage, test tubes and a calibrated serofuge.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. The condition and appearance of the specimens are a part of this study.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Perform routine testing for administration of Rh immune globulin.
  - a. Check patient record for evidence of antenatal administration of Rh immune globulin.
  - b. Perform Rh(D) and weak D type.
  - c. Perform antibody screening.
  - d. Determine eligibility for Rh immune globulin administration considering
    - (1) Rh(D) and weak D type,
    - (2) Antenatal administration of Rh immune globulin,
    - (3) Results of antibody screening.
  - e. Quantitate fetal maternal hemorrhage using the Kelihauer-Betke or Rosette techniques.

#### Record, Evaluate and Report Results:

- 6. Evaluate control results in relationship to study findings. Report to the technical supervisor or laboratory director and in consultation, following written procedures, calculate dosage of Rh immune globulin based on test results.
- 7. Issue Rh immune globulin and complete appropriate records.

#### Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the theory behind the prevention of hemolytic disease of the newborn with the use of Rhimmune globulin. Explain the principle of the Rosette and the Kleihauer-Betke

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

#### Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The mother typed D negative and had anti-D in her serum. The baby typed D negative with a positive direct antihuman globulin test (DAT). Suggest a reason why the baby typed negative and outline an appropriate course of action.



## IMMUNOHEMATOLOGY AND TRANSFUSION MEDICINE

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Suspected transfusion reaction either nonhemolytic or hemolytic Supervision of a technical supervisor or laboratory director

Facility-specific protocol and procedures

Reagents

Test tubes

Saline

Serofuge

OSHA-recommended personal protective equipment

NOTE: Examples of a nonhemolytic transfusion reaction include a febrile nonhemolytic reaction, an allergic reaction, an anaphylactic reaction, a bacterial contamination circulatory overload, a noncardiogenic pulmonary edema, a post transfusion purpura hemosiderosis or graft versus host disease. Examples of a hemolytic transfusion reaction include acute nonimmune hemolysis or acute immune hemolysis.

#### **WORK TO BE PERFORMED**

Investigate a suspected transfusion reaction.

#### **PERFORMANCE CRITERIA**

Criteria for acceptable performance include 100% accuracy in testing and in completing documentation. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens. Given the type of reaction and complicating factors, an investigation requires from three to ten hours.

### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Blood samples from the patient and from the blood products transfused are required. Urine is also requested.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents to include ABO, Rh typing sera, antihuman globulin and set of antigens; test tubes; saline; and serofuge.



#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluation of specimens and documentation of their appearance are parts of the transfusion reaction investigation.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Perform clerical check on previous testing, if available.
- 6. Draw an EDTA tube from the recipient and examine for hemolysis.
- 7. Collect a urine specimen and test for the presence of hemoglobin and red blood cells.
- 8. Perform a direct antihuman globulin test (DAT) on the pre- and post-patient specimens.
- 9. If any of the above screens are positive,
  - a. Implement preliminary investigation to determine whether a hemolytic reaction has occurred.
    - (1) Check identification of pretransfusion patient and donor samples and blood container.
    - (2) Confirm correctness of interpretation of pretransfusion test results.
    - (3) Compare pretransfusion and post-transfusion specimens to include color of serum and direct antiglobulin test.
    - (4) Check post-transfusion sample for evidence of hemolysis.
  - b. Analyze preliminary test results to determine whether a hemolytic reaction has occurred.
  - c. Conduct investigation to determine cause of hemolytic transfusion reaction.
    - (1) Repeat ABO and Rh compatibility and antibody screening test on the pretransfusion and post-transfusion recipient samples, appropriate donor samples and blood from the donor bag(s).
    - (2) Identify any unexpected antibodies detected in recipient's serum.
    - (3) Phenotype donor cells for antigens corresponding to recipient antibodies detected in recipient serum.
    - (4) Use enhancement techniques for compatibility tests to detect weakly reactive antibodies.
    - (5) Analyze all data to identify cause of transfusion reaction.
    - (6) Prepare and test a red cell eluate when the direct antihuman globulin test is positive for IgG.
  - d. Investigate non-immunologic causes of hemolysis.
    - (1) Gram stain and culture blood from bag.
    - (2) Examine contents of blood bag and transfusion set for evidence of hemolysis.
    - (3) Examine donor plasma for hemolysis and investigate cause such as proper storage.
  - e. Select appropriate blood for future transfusions that will not cause a similar reaction.
  - f. Investigate suspected case of transfusion-associated infectious disease.
    - (1) Report testing results to blood suppliers and appropriate regulatory agencies.

#### Record, Evaluate and Report Results:

10. Evaluate all findings in relationship to control results and patient status. Report to the technical supervisor or laboratory director for interpretation, reporting and action.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

11. Clean work area with disinfectant. Remove gloves and discard. Wash hands.



## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain the purpose of each step of a transfusion reaction and features to distinguish nonhemolytic from hemolytic reactions and the signs and symptoms of a transfusion reaction.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 100% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The recipient's temperature was 101.6°F at the beginning of the transfusion. A registered nurse calls the transfusion service to report a transfusion reaction because the patient's temperature had risen to 102°F. Interpret this response and suggest an appropriate course of action.



## IMMUNOHEMATOLOGY AND TRANSFUSION MEDICINE

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Suspected case scenarios

Appropriate specimens ranging from mother's blood to specimens from amniocentesis and/or baby's blood post partum

Reagents

Controls

Supervision of a technical supervisor or laboratory director

Facility-specific protocol and related procedures

Test tubes

Serofuge

Mechanism to wash cells

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Investigate hemolytic disease of the newborn to include prenatal testing on maternal sample, preparing blood for intrauterine transfusion, performing neonatal testing and/or performing testing for exchange transfusion.

#### PERFORMANCE CRITERIA

Criteria for acceptable performance requires 100% accuracy. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown specimens including a full range of reactivity.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. Depending on the phase of the investigation, specimens may represent maternal, fetal or baby's blood.

Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls, test tubes, serofuge and a mechanism to wash cells.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Select the correct sample for the studies required.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Perform prenatal testing on maternal sample.
  - a. Perform ABO and Rh typing.
  - b. Perform antibody screening and identification.
  - c. Perform, if required, antibody titer.
- 6. Procure safe blood for intrauterine transfusion.
  - a. Select fresh blood of appropriate type.
  - Select/prepare leukocyte reduced, sickle cell negative, irradiated or cytomegalovirus seronegative donors as necessary.
  - c. Perform compatibility testing using maternal serum, eluate or fetal serum when available through umbilical cord sampling.
- 7. Perform neonatal testing.
  - a. Perform ABO and Rh typing.
  - b. Perform direct antiglobulin testing.
  - c. Perform elution.
- 8. Perform testing for exchange transfusion.
  - a. Select blood for transfusion that is appropriate to the clinical needs of the recipient (fresh, leukocyte reduced, sickle cell negative, irradiated or cytomegalovirus seronegative units).
  - b. Perform compatibility test using appropriate samples.

#### Record, Evaluate and Report Results:

9. Predict risk for HDN from parental phenotypes. Report results to the technical supervisor or laboratory director for interpretation, reporting and action.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

10. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test to explain conditions that lead to hemolytic disease of the newborn; explain the most common cause of dosage-initiating HDN; describe the pathology related to HDN; correlate HDN to observations on the peripheral smear; outline steps to prevent HDN, where possible; and correlate the bilirubin pigment in amniotic fluid to the severity of the HDN.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. These include instrument maintenance and function checks of the serofuges.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.



Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 100% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A cord blood specimen is collected. The cells fail to react to typing sera. Suggest a corrective course of action.



## IMMUNOHEMATOLOGY AND TRANSFUSION MEDICINE

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Supply of blood products
Correctly identified recipient
Completed request
Supervision of a technical supervisor or laboratory director
Facility-specific protocol and related procedures
OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Issue blood and blood products to include blood, pool platelets, pool/thawed cryoprecipitate and thawed fresh-frozen and single-donor plasmas. Prepare red blood cells to specified hematocrits or small volumes for pediatric patients.

#### **PERFORMANCE CRITERIA**

Criteria for acceptable performance is 100% accuracy in issuing the correct component to the identified patient. Most fatal transfusion reactions are due to clerical errors resulting in an ABO incompatible transfusion.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

Check patient identification using the protocol specified in the facility.
Compare ABO and Rh of patient with those of donor. Before a blood
component can be started, the blood product label, the attached compatibility
tag and the patient's wristband must be compared to assure that the first and
last names as well as the unique identifying numbers are the same and that
ABO/Rh types of this product and the recipient are compatible.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. When handling blood and components, wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment:

3. Ensure that rotators for platelets and other equipment are calibrated and controlled.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Upon receipt, inspect blood and blood products for evidence of contamination, deterioration or expiration.



- 5. Maintain inventory of blood and blood products.
- 6. Perform confirmatory verification of ABO group and Rh type on all received

#### Perform Procedure and Quality Control; Document and Evaluate:

7. Prepare products for infusion according to written procedures. Products include pooled platelets, cryoprecipitate and fresh-frozen donor plasma. Special procedures include preparing red blood cells to specified hematocrits or small volumes for pediatric patients.

#### Record, Evaluate and Report Results:

- 8. Complete all records including time of issuance.
- 9. Inspect all returned products for evidence of improper storage. Prepare to reissue or dispose. Report any divergence from protocol to technical supervisor or laboratory director.

#### Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

10. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a written test describing each blood product and component, its appropriate use in transfusion therapy, procedures and protocols for maintaining and issuing these products and storage requirements.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Not applicable.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A unit of blood was returned to the transfusion section of the laboratory. It was warm to the touch. The nurse said the unit had sat at room temperature for 45 minutes. Suggest the appropriate course of action.



#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens

Two levels of controls

Methods for performing these tests (ion selective electrodes)

A procedure

Reagents

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Demonstrate tests for sodium, chloride and potassium. Other electrolytes that may be tested include carbon dioxide, ionized calcium, magnesium, phosphate or lactate.

#### **PERFORMANCE CRITERIA**

Criteria for acceptable performance for the electrolytes are as follows:

**ANALYTE** 

CRITERIA FOR ACCEPTABLE PERFORMANCE

Chloride

Target Value ±5%

Sodium

Target Value ±4 mmol/L

Potassium

Target Value ±0.5 mmol/L

A minimum of five challenge samples must demonstrate a full range of material that describes results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on whole blood, plasma, serum, urine or sweat.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain equipment including deproteininzing and calibrating electrodes. Quality control procedures require that instruments be calibrated or that calibration be verified according to manufacturer's specifications with at least the frequency recommended.



#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into the ion-selective electrode.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the electrolyte results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on the same test or other test results on the same patient.
  - g. Determine any need for repeat analysis on new specimens or need for any additional testing.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.



#### ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of potentiometry in the ion selective electrode for whole blood, serum or plasma; explain the role of electrolytes in the human body; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The specimen is hemolyzed. The potassium level exceeds the upper limit of linearity. Suggest a reasonable corrective action.



PERFORM TESTS FOR ENZYMES (ALANINE AMINOTRANSFERASE, ALKALINE PHOSPHATASE, AMYLASE, ASPARTATE AMINOTRANSFERASE, CREATINE KINASE, LACTATE DEHYDROGENASE AND GAMMAGLUTA TRANSFERASE).

**CHEMISTRY** 

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens

Two levels of controls

Methods for performing a selection of theses enzymes

A procedure

Reagents

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Perform tests for enzymes demonstrating the use of kinetics.

#### PERFORMANCE CRITERIA

Criteria for acceptable performance for the electrolytes are as follows:

## CRITERIA FOR ANALYTE ACCEPTABLE PERFORMANCE

Alanine aminotransferase	Target value ±20%
Alkaline phosphatase	Target value ±30%
Amylase	Target value ±30%
Aspartate aminotransferase	Target value ±20%
Creatine kinase	Target value ±30%
Lactate dehydrogenase	Target value +20%

A minimum of five challenge samples must demonstrate a full range of materials that describe results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

 The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on serum.



#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

Assemble reagents, controls and unknowns. Maintain equipment especially
verifying the temperature control of the enzymatic reactions. Quality control
procedures require that instruments be calibrated or that calibration be verified according to manufacturer's specifications with at least the frequency
recommended.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- Perform procedure. Introduce samples and controls into the ion-selective electrode.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the enzyme results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.



- d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
- e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
- f. Evaluate whether results fit expected pattern with respect to previously obtained results on same test or other test results on same patient.
- g. Determine any need for repeat analysis on new specimens or need for any additional testing.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

#### ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of enzyme kinetics including reactions and rates; explain the significance of each of the enzymes in normal body chemistry and in pathology; state the significance of each diagnostic enzyme; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The specimen is hemolyzed. The lactate dehydrogenase level exceeds the upper limit of linearity. Suggest a reasonable corrective action.



**CHEMISTRY** 

#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens

Two levels of controls

Methods for performing a selection of these therapeutic medications A procedure

#### **WORK TO BE PERFORMED**

Perform tests for levels of therapeutic medications.

#### PERFORMANCE CRITERIA

ANALYTE

Criteria for acceptable performance for the electrolytes are as follows:

#### CRITERIA FOR ACCEPTABLE PERFORMANCE

Carbamazepine	Target value ± 25%
Digoxin	Target value $\pm 20\%$ or $\pm 0.2$ ng/mL
Ethosuximide	Target value ± 20%
Gentamicin	Target value ± 25%
Lithium	Target value $\pm 0.3$ mmol/L
Phenobarbital	Target value ± 20%
Phenytoin	Target value ± 25%
Primidone	Target value $\pm 25\%$
Procainamide	Target value $\pm 25\%$
Quinidine	Target value ± 25%
Tobramycin	Target value $\pm 25\%$
Theophylline	Target value $\pm 25\%$
Valproic Acid	Target value $\pm 25\%$

A minimum of five challenge samples must demonstrate a full range of material that describe results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation

1. The unknown samples may be provided. If collection of specimens are required for testing, note special precaution related to drawing that must be observed. Tests may be performed on serum.



#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personl Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain equipment, especially verifying the temperature control of the enzymatic reactions. Quality control procedures require that instruments be calibrated or that calibration be verified according to manufacturer's specifications with at least the frequency recommended.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation, specimen identification and labeling and the type of specimen. Note use of anticoagulant, if any, time of collection and processing, site of collection, adequacy of specimen quantity and proper transport and storage. Check for hemolysis and lipemia which will interfere with some of the results. Note potential interfering substances.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test:
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation; consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks when required. Identify and correct any malfunction employing established trouble-shooting protocol. Document results of calibration, performance and maintenance checks and malfunctions and corrections.
- 6. Perform procedure; introduce samples and controls into the ion-selective electrode.
  - a. Include controls and standards at the intervals as required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the electrolyte results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results considering the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.

- e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
- f. Evaluate whether results fit expected pattern with respect to previously obtained results on same test or other test results on same patient.
- g. Determine any need for repeat analysis on new specimens or any additional testing.

Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

### ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better to explain the principle of dose effect relationships, steady state and the clinical utility of therapeutic drug monitoring; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements including instrument maintenance and function checks.

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem Solving Skills:

Example: The blood for therapeutic drug levels was collected one hour post dose. Evaluate and, if appropriate, suggest a corrective course of action.



#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens

Two levels of control

A method and an instrument for performing this test

A procedure

Reagents

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Perform a test for uric acid.

#### **PERFORMANCE CRITERIA**

Criteria for acceptable performance for uric acid is the target value ±17%. A minimum of five challenge samples must demonstrate a full range of samples that describe results expected in unknown samples ranging from abnormal low to abnormal high values.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Test may be performed on plasma, serum or urine.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain equipment. Quality control procedures require that instruments be calibrated or that calibration be verified according to manufacturer's recommended frequency and specifications.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into the instrument.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the electrolyte results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on same test or other test results on same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principles of absorbance, color formation and light scatter in methods for determining uric acid results; explain the role of uric acid in the human body; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.



#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Both levels of control are within the established two standard deviation limits. The uric acid is two times the upper limit of the reference range. What corrective action may be required?



#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens

Two levels of controls

Methods for performing a test for blood urea nitrogen

A procedure

Reagents

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Demonstrate test for determining levels of blood urea nitrogen.

#### **PERFORMANCE CRITERIA**

Criteria for acceptable performance of a test for blood urea nitrogen is target value  $\pm 2$  mg/dL or  $\pm 9\%$ . A minimum of five challenge samples must demonstrate a full range of materials that describes results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

## PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on plasma, serum or urine.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain equipment. Quality control procedures require that instruments be calibrated or that calibration be verified according to manufacturer's recommended frequency and specifications.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into the instrument.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the urea nitrogen results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on same test or other test results on same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

### **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of the methods for determining urea nitrogen; explain the role of urea nitrogen in the human body; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)



Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A tube of blood drawn for a blood urea nitrogen was found at the end of the shift. The tube has been at room temperature for seven hours. Suggest a course of action.



#### **SKILL STANDARD**

#### **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens

Two levels of controls

Methods for performing a test for creatinine

A procedure

Reagents

OSHA-recommended personal protective equipment

#### **WORK TO BE PERFORMED**

Demonstrate test for determining levels of creatinine.

#### PERFORMANCE CRITERIA

Criteria for acceptable performance of a test for creatinine is target value ±0.3 mg/dL or ±15%. A minimum of five challenge samples must demonstrate a full range of materials that describe results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

### PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on plasma, serum or urine.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

Assemble reagents, controls and unknowns. Maintain equipment. Quality
control procedures require that instruments be calibrated or that calibration be
verified according to manufacturer's recommended frequency and
specifications.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into the instrument.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the creatinine results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on the same test or other test results on the same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.

## Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

## **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of the methods for determining creatinine; explain the role of creatinine in the human body; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.



#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: After centrifugation, the serum appear icteric. Suggest an appropriate course of action.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens Two levels of controls Methods for performing a test for protein A procedure

### **WORK TO BE PERFORMED**

Demonstrate test for determining levels of protein.

### PERFORMANCE CRITERIA

Criteria for acceptable performance of a test for protein is target value ±10%. A minimum of five challenge samples must demonstrate a full range of materials that describe results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on plasma, serum or urine.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain equipment. Quality control procedures require that instruments be calibrated or that calibration be verified according to manufacturer's recommended frequency and specifications.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis and lipemia which will interfere with some of the results. Note potential interfering substances.



### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into the instrument.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the protein results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on same test or other test results on same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of the methods for determining protein; explain the role of protein in the human body; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.



#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: After centrifugation, the specimen appears lipemic. Suggest a reasonable corrective action, if required.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens
Two levels of controls

Methods for performing a test for protein

A procedure

Reagents

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate test for determining levels of albumin.

### PERFORMANCE CRITERIA

Criteria for acceptable performance for albumin is target value ±10%. A minimum of five challenge samples must demonstrate a full range of materials that describe results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on plasma, serum or urine.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain equipment. Quality control procedures require that instruments be calibrated or that calibration be verified according to manufacturer's recommended frequency and specifications.

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into instrument provided.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the albumin results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on the same test or other test results on the same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of the methods for determining albumin; explain the role of albumin in the human body; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity. Correlate out-of-reference range results with possible disease states.



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#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The patient base is comprised of pregnant women. The albumin results are all below the published reference range. Both the normal and abnormal results are within acceptable limits. Suggest a reasonable corrective course of action, if required.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens

Two levels of controls

Methods for performing a test for glucose

A procedure

Reagents

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate test for determining levels of glucose.

### PERFORMANCE CRITERIA

Criteria for acceptable performance for glucose is target value  $\pm 6$  mg/dL or  $\pm 10\%$ . A minimum of five challenge samples must demonstrate a full range of materials that describe results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

 The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on whole blood, plasma, serum or urine.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

Assemble reagents, controls and unknowns. Maintain equipment. Quality
control procedures require that instruments be calibrated or that calibration be
verified according to manufacturer's recommended frequency and
specifications.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into instrument provided.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the albumin results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on the same test or other test results on the same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of the methods for determining glucose; explain the role of glucose in the human body; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.



#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A specimen was centrifuged upon clotting; the serum was separated from the cells and stored at 4° centigrade. Twenty-four hours later, the physician calls to request a glucose on this specimen. Suggest a corrective course of action, as required.



PERFORM SCREENING TEST FOR DRUGS OF ABUSE (PHENCYCLIDINE, BENZODIAZEPINES, COCAINE [BENZOYL ECGONINE], AMPHETAMINES, THC, OPIATES, BARBITURATES, TRICYCLIC ANTIDEPRESSANTS).

**CHEMISTRY** 

# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens Two levels of controls Methods for performing a test for glucose A procedure

# **WORK TO BE PERFORMED**

Demonstrate a competitive binding immunoassay or chromatographic procedure for the qualitative determination of the presence of the major metabolites of drugs of abuse.

### PERFORMANCE CRITERIA

Criteria for acceptable performance for qualitative test require positive and negative controls. A minimum of five challenge samples must demonstrate a full range of materials that describe results expected in unknown specimens.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to collection that must be observed. Tests are performed on urine.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for adulteration which will interfere with some of the results. Note potential interfering substances.



#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents and controls.
    - (1) Use appropriate pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
- 6. Perform procedure. Introduce samples and controls. Include controls as required by protocol.

#### Record, Evaluate and Report Results:

- 7. Determine the results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - b. Evaluate whether results fit expected pattern with respect to previously obtained results on the same test or other test results on the same patient.
  - c. Determine any need for repeat analysis on new specimens or any additional testing.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of the qualitative competitive binding or chromatographic methods for identifying urinary metabolites of the most common classes of drugs of abuse; explain the purpose and the precautions related to the requested test to other health care personnel (in particular the need for confirmation of positive results); recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

# Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

#### Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: A color bar appears in the negative control lane. Suggest explanations for this observation and suggest a corrective course of action.



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# SKILL STANDARD

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens

Three levels of controls

Methods for performing these tests (electrodes)

A procedure

Reagents

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate tests for pH, pO, and pCO,

# PERFORMANCE CRITERIA

Criteria for acceptable performance for the electrolytes are as follows:

#### ANALYTE CRITERIA FOR ACCEPTABLE PERFORMANCE

pН

Target Value +0.04

 $pO_2$ 

Target Value ±3 Standard Deviations

pCO

Target Value ±5 mm Hg or ±8%

A minimum of five challenge samples must demonstrate a full range of material that describe results expected in unknown specimens. A minimum of three levels of control, one with values representing expected reference ranges of a healthy individual and the second and third with values representing pathologic conditions, meet the criteria established for acceptance.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing arterial or venous samples for blood gases that must be observed. Tests are performed on whole blood.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain equipment including deproteining and calibrating electrodes. Quality control procedures require that instruments be calibrated or that calibration be verified according to manufacturer's recommend frequency and specifications.



#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation, specimen identification and labeling, the type of specimen, use of anticoagulant, time of collection and processing, site of collection, adequacy of specimen quantity and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.

### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- Perform procedure. Introduce samples and controls into the ion-selective electrode.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the electrolyte results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on the same test or other test results on the same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# ASSESSMENT AND CREDENTIALING APPROACH

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of potentiometry in the determination of blood gases in whole blood; explain the role of blood gases in the human body; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.



#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: The specimen is hemolyzed. Suggest a reasonable course of action.



**CHEMISTRY** 

### **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Spectrophotometer

Reagents

Serum and cholesterol standards and controls

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Manually perform a test for determining the concentration of cholesterol in the serum.

### PERFORMANCE CRITERIA

The cholesterol result must be reported within  $\pm 10\%$  of the target value; both the high and low control must have met the criteria for acceptable performance. The test result must be reported within 30 minutes.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on plasma or serum.

### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain spectrophotometer. Quality control procedures require that instruments be calibrated or that calibration be verified.

### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.



### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into instrument provided.
  - a. Prepare cholesterol reagent according to instructions. Turn on spectrophotometer and set wavelength to 500 NM.
  - b. Set the absorbance reading to zero using water as the blank.
  - c. Label test tubes as blank, calibrator, control and sample.
  - d. Warm the reagent to the temperature being used for the assay.
  - e. Pipette 1.0 mL reagent into each of the prepared tubes.
  - f. Add 0.01 mL of reagent into each of the prepared tubes.
  - g. Add 10 uL of calibrator, control and sample into the appropriately labeled tubes. Cover with parafilm or stopper and mix tubes by gentle inversion.
  - h. Incubate the tubes for five minutes at 37° centigrade or ten minutes at 25-30° centigrade.
  - Read and record absorbance of all tubes at 500 NM.
  - Calculate the total cholesterol in sample and control using the absorbance formula.

Serum

cholesterol = A(test) - A(blank) x Calibrator (mg/dL)

mg/dL A(calibrator) - A(blank)

#### Record, Evaluate and Report Results:

- 7. Determine the various cholesterol results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on the same test or other test results on the same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

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# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of the method for determining cholesterol and its role in the human body; explain the pathology associated with elevated cholesterol; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: How would cholesterol results be different if all tubes were read at 600 NM instead of 500 NM?



**CHEMISTRY** 

### **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE.**

#### Given the following:

Minimum of five unknown specimens

Standard

Two levels of control

Methods for performing tests for lipids such as cholesterol including HDL and triglycerides

**Procedures** 

Reagents

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate test for determining cholesterol, HDL and triglyceride levels including calculations for LDL as appropriate.

### PERFORMANCE CRITERIA

Criteria for acceptable performance for the electrolytes are as follows:

#### **ANALYTE**

#### CRITERIA FOR ACCEPTABLE PERFORMANCE

Cholesterol Total High Density Lipoprotein

Target Value ±10% Target Value ±30%

Triglycerides

Target Value ±25%

A minimum of five challenge samples must demonstrate a full range of materials that describe results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on plasma or serum.

#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.



### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain equipment. Quality control procedures require that instruments be calibrated or that calibration be verified according to manufacturer's recommended frequency and specifications.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into instrument provided.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the various lipid results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - c. Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on the same test or other test results on the same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.

# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.



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# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of the various methods of performing lipid analysis; explain the role of lipids in the human body; explain the pathology associated with elevated lipids; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Specimens are lipemic. Evaluate and suggest a corrective course of action.



# **SKILL STANDARD**

# **CONDITIONS OF PERFORMANCE**

#### Given the following:

Minimum of five unknown specimens

Two levels of controls

Methods for performing these tests

A procedure

OSHA-recommended personal protective equipment

# **WORK TO BE PERFORMED**

Demonstrate tests of the endocrine system for cortisol, free thyroxine, human chorionic gonadotropin, T3 Uptake, triiodothyronine, thyroid stimulating hormone and thyroxine.

### **PERFORMANCE CRITERIA**

ANALYTE

Criteria for acceptable performance for the electrolytes are as follows:

# CRITERIA FOR ACCEPTABLE PERFORMANCE

Cortisol	Target Value ±25%
Free Thyroxine	Target Value +3 SD

Human Chorionic

Gonadotropin Target Value ±3 SD
T3 Uptake Target Value ±3 SD
Triiodothyronine Target Value ±3 SD

Thyroid Stimulating

Hormone Target Value ±3 SD
Thyroxine Target Value ±3 SD

A minimum of five challenge samples must demonstrate a full range of material that describe results expected in unknown specimens. A minimum of two levels of control, one with values representing expected reference ranges of a healthy individual and the second with values representing pathologic conditions, meet the criteria established for acceptance.

# PERFORMANCE ELEMENTS AND ASSESSMENT CRITERIA

#### Client Preparation:

1. The unknown samples may be provided. If collection of specimens is required for testing, note special precautions related to drawing that must be observed. Tests may be performed on plasma or serum.



#### Comply with Occupational Safety and Health Administration Standards; Demonstrate Use of Personal Protective Equipment:

(Includes the OSHA Occupational Exposure to Bloodborne Pathogens Standards)

2. Wash hands and put on gloves and other personal protective equipment.

#### Assemble, Maintain and Monitor Equipment, Reagents and Controls:

3. Assemble reagents, controls and unknowns. Maintain equipment including deproteinizing and calibrating electrodes. Quality control procedures require that instruments be calibrated or that calibration be verified according to manufacturer's recommended frequency and specifications.

#### Evaluate Sample/Specimen for Acceptability or Rejection:

4. Evaluate the suitability of the specimens including adequacy of patient preparation; specimen identification and labeling; the type of specimen; use of anticoagulant, if any; time of collection and processing; site of collection; adequacy of specimen quantity; and proper transport and storage. Check for hemolysis, lipemia and elevated protein which will interfere with some of the results. Note potential interfering substances.

#### Perform Procedure and Quality Control; Document and Evaluate:

- 5. Prepare to perform test.
  - a. Prepare/reconstitute reagents, standards and controls. Prepare instrument.
    - (1) Use appropriate glassware/pipettes for accurate preparation.
    - (2) Observe for contamination or deterioration and for expiration dates.
    - (3) Note appropriateness of storage conditions for reagents.
  - b. Prepare specimens for analysis using the appropriate technique.
    - (1) Centrifugation consider speed, temperature and time.
    - (2) Separate cells from serum/plasma.
    - (3) Make any required dilutions including determination of the appropriate volumes for the specified dilator and the correct diluent.
  - c. Perform calibration, performance and maintenance checks. When required, identify and correct any malfunction employing established troubleshooting protocol. Document results of calibration, performance and maintenance checks; malfunctions; and corrections.
- 6. Perform procedure. Introduce samples and controls into the instrument.
  - a. Include controls and standards at the intervals required by protocol.
  - b. Create a log for the positioning of samples, controls and standards.

#### Record, Evaluate and Report Results:

- 7. Determine the results including the evaluation of controls as a decision element in relationship to accepting and subsequent reporting of sample results. Consider the following factors:
  - a. Report unknown/client results using established significant numbers.
  - b. Note panic and/or alert values, and follow established protocol for stat reporting and documentation.
  - Identify reference values for analytes. Recognize normal and abnormal results.
  - d. Recognize values that are significantly different to include risk values, panic values and potential analytical errors.
  - e. Correlate laboratory results with patient information including patient history, medication, diagnosis and physiologic conditions.
  - f. Evaluate whether results fit expected pattern with respect to previously obtained results on the same test or other test results on the same patient.
  - g. Determine any need for repeat analysis on new specimens or any additional testing.



# Segregate, Handle, Recycle or Dispose of Chemical, Biohazardous and/or Infectious Waste:

8. Clean work area with disinfectant. Remove gloves and discard. Wash hands.

# **ASSESSMENT AND CREDENTIALING APPROACH**

#### Pass Written Test of Principles:

Competence is demonstrated by a score of 90% or better on a test to explain the principle of the test procedures; explain the role of the endocrine hormones in the human body; explain the purpose of the requested test to other health care personnel; recognize interfering substances and their effects; and explain the limitations of the method and instrument with respect to sensitivity, specificity, precision and linearity.

#### Demonstrate Procedure/Skill under Direct Observation:

Requires 100% compliance with performance elements. (These include instrument maintenance and function checks.)

Demonstrate Successful Performance with a Proficiency Sample, a Blind or Split Sample or Other Previously Analyzed Sample Matching Results to Recorded or Published Standards:

Wherever possible, the criteria for acceptable performance follow published industry standards as demonstrated through proficiency testing.

Complete Documentation of Worksheets, Recording and Reporting of Test Results, Reports, Quality Control, Maintenance Logs and Proficiency Testing:

Competence is demonstrated through 95% compliance with complete documentation.

#### Demonstrate Problem-Solving Skills:

Example: Both the high and low controls are three standard deviations above the mean. Suggest a course of action.



Academic Skills	Skills (and related knowledge) contained in the subject areas and disciplines addressed in most national and state educational standards, including English, mathematics, science, etc.		
Assessment	A process of measuring performance against a set of standards through examinations, practical tests, performance observations and/or the completion of work portfolios.		
Content Standard	A specification of what someone should know or be able to do to successfully perform a work activity or demonstrate a skill.		
Critical Work Functions	Distinct and economically meaningful sets of work activities critical to a work process or business unit which are performed to achieve a given work objective with work outputs that have definable performance criteria. A critical work function has three major components:		
	<ul> <li>Conditions of Performance: The information, tools, equipment and other resources provided to a person for a work performance.</li> </ul>		
	<ul> <li>Work to Be Performed: A description of the work to be performed.</li> </ul>		
	<ul> <li>Performance Criteria: The criteria used to determine the required level of performance. These criteria could include product characteristics (e.g., accuracy levels, appearance), process or procedure requirements (e.g., safety, standard professional procedures) and time and resource requirements. The IOSSCC requires that these performance criteria be further specified by more detailed individual performance elements and assessment criteria.</li> </ul>		
Credentialing	The provision of a certificate or award to an individual indicating the attainment of a designated set of knowledge and skills and/or the demonstration of a set of critical work functions for an industry/occupational area.		
Illinols Occupational Skill Standards and Credentialing Council (IOSSCC)	Legislated body representing business and industry which establishes skill standards criteria, endorses final products approved by the industry subcouncil and standards development committee and assists in marketing and dissemination of occupational skill standards.		
industry	Type of economic activity, or product or service produced or provided in a physical location (employer establishment). They are usually defined in terms of the Standard Industrial Classification (SIC) system.		



Industry Subcouncil	Representatives from business/industry and education responsible for identifying and prioritizing occupations for which occupational performance skill standards are adapted, adopted or developed. They establish standards development committees and submit developed skill standards to the IOSSCC for endorsement. They design marketing plans and promote endorsed skill standards across the industry.	
Knowledge	Understanding the facts, principles, processes, methods and techniques related to a particular subject area, occupation or industry.	
Occupation	A group or cluster of jobs, sharing a common set of work functions and tasks, work products/services and/or worker characteristics. Occupations are generally defined in terms of a national classification system including the Standard Occupational Classification (SOC), Occupational Employment Statistics (OES) and the Dictionary of Occupational Titles (DOT).	
Occupational Cluster	Grouping of occupations from one or more industries that share common skill requirements.	
Occupational Skill Standards	Specifications of content and performance standards for critical work functions or activities and the underlying academic, workplace and occupational knowledge and skills needed for an occupation or an industry/occupational area.	
Occupational Skills	Technical skills (and related knowledge) required to perform the work functions and activities within an occupation.	
Performance Standard	A specification of the criteria used to judge the successful performance of a work activity or the demonstration of a skill.	
Product Developer	Individual contracted to work with the standard development committee, state liaison, industry subcouncil and IOSSCC for the adaptation, adoption or development of skill standards content.	
Reliability	The degree of precision or error in an assessment system so repeated measurements yield consistent results.	
Skill	A combination of perceptual, motor, manual, intellectual and social abilities used to perform a work activity.	



Skill Standard	Statement that specifies the knowledge and competencies required to perform successfully in the workplace.  Incumbent workers, supervisors and human resource persons within the industry who perform the skills for which standards are being developed. Secondary and postsecondary educators are also represented on the committee. They identify and verify occupational skill standards and assessment mechanisms and recommend products to the industry subcouncil for approval.			
Standards Development Committee				
State Llaison	Individual responsible for communicating information among all parties (IOSSCC, subcouncil, standard development committee, product developer, project director, etc.) in skill standard development.			
Third-Party Assessment	An assessment system in which an industry-designated organization (other than the training provider) administers and controls the assessment process to ensure objectivity and consistency. The training provider could be directly involved in the assessment process under the direction and control of a third-party organization.			
Validity	The degree of correspondence between performance in the assessment system and job performance.			
Workplace Skills	The generic skills essential to seeking, obtaining, keeping and advancing in any job. These skills are related to the performance of critical work functions across a wide variety of industries and occupations including problem solving, leadership, teamwork, etc.			



# ILLINOIS OCCUPATIONAL SKILL STANDARDS AND CREDENTIALING COUNCIL

Margaret Blackshere	AFL-CIO	
David Emerson	Downstate National Bank	· · · · · · · · · · · · · · · · · · ·
Michael O'Neill	Chicago Building Trades Council	
Janet Payne	United Samaritans Medical Center	
Gerald Schmidt	Illinois Manufacturing Association Caterpillar	÷
Jim Schultz	Illinois Retail Merchants Association Walgreen Company	<u> </u>
Larry Vaughn	Illinois Chamber of Commerce	



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	Freeport Memorial Home Health Care		



Gloria Tarvin	Chairperson of Allied Health/Nursing Rehabilitative Institute of Chicago		
Dr. Watter Zinn	Optometrist		
Kathryn Torricelli	State Liaison Illinois State Board of Education		



# CLINICAL LABORATORY SCIENCE/BIOTECHNOLOGY CLUSTER STANDARDS DEVELOPMENT COMMITTEE

# **APPENDIX D**

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	V.A. Medical Center
Dave Hooper	Laboratory Technician
	Science Instructor
	Joliet West High School
Valerie Johnson	Training Advisor
	Centers for Disease Control & Prevention
Maria Kaminski	Lab Quality Administrator
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	Illinois Department of Public Health
Janice Kinsinger	Professor, Health Occupations
	Department Program Director
	Medical Laboratory Technician & Phlebotomy Program
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Tina Reno	Laboratory Manager
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	Medical Laboratory Sciences Program
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Jane Adrian	Product Developer
	Director, Clinical Laboratory
	Illinois Department of Mental Health and Developmental Disabilities
Vothum Tomicelli	-
Kathryn Torricelli	State Liaison
	Illinois State Board of Education



### **APPENDIX E**

#### I. Occupational Definition and Justification

#### A. Occupational Definitions

The skills embodied in laboratory sciences are rapidly expanding beyond the traditional clinical setting into the many opportunities in biotechnology. This cluster of skills describes standards appropriate to the clinical or medical lab as well as any laboratory setting in which these operations are performed for diagnostic or research purposes.

- 1. Clinical Laboratory Scientist/Medical Technologist is an individual who supervises, teaches and delegates and provides services in clinical laboratory sciences. The clinical laboratory scientist/medical technologist is responsible for his/her actions, relates to people, exhibits a capacity for calm and reasoned judgement, demonstrates a commitment to client requirements and demonstrates ethical and moral attitudes and principles. The clinical laboratory scientist/medical technologist demonstrates an attitude of respect for the client and maintains confidentiality. In laboratories accredited by the Health Care Financing Administration, the clinical laboratory scientist may qualify as the laboratory director, the technical consultant and testing personnel in a laboratory performing moderately complex testing and as technical supervisors, general supervisors and testing personnel in a laboratory performing highly complex testing. These individuals are competent in
  - a. developing and establishing procedures for collection, processing and analyzing biological specimens and samples from a variety of sources;
  - b. performing tests from a variety of biological sources to include body fluids, cells and other substances;
  - c. integrating and relating data generated from a variety of sources while making decisions regarding possible discrepancies;
  - d. confirming abnormal results, verifying quality control procedures, executing quality control procedures and developing solutions to problems concerning the generation of laboratory data;
  - e. making decisions concerning the results of quality control and quality assurance measures and instituting proper procedures to maintain accuracy and precision;
  - f. establishing and performing preventive and corrective maintenance of equipment and instruments as well as identifying appropriate sources for repairs;
  - g. developing and evaluating and selecting new techniques, instruments and methods in terms of their usefulness and practicality within the context of a given laboratory's personnel, equipment, space and budgetary resources;
  - h. demonstrating professional conduct and interpersonal skills with clients, laboratory personnel, other health care professionals and the public;
  - i. establishing and maintaining competency and continuing education as a function of growth and maintenance of professional competence;
  - j. exercising leadership in education of other health personnel and the community;
  - k. exercising principles of management, safety and supervision, educational methodology and current information systems.
     (Adapted from the National Accrediting Agency for Clinical Laboratory Sciences-Essentials)
- 2. Clinical Laboratory Technician/Medical Laboratory Technician is an individual who performs testing of all types in a variety of settings. In the case of reporting results for purposes of diagnoses or therapeutic monitoring of humans, tests are performed and reported under the direction of the technical supervisor or laboratory director. In laboratories accredited by the Health Care Financing Administration, the clinical laboratory technician may qualify as a general supervisor and as testing personnel in laboratories performing highly complex testing and as testing personnel in laboratories



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performing moderately complex testing. Clinical laboratory technicians/medical laboratory technicians are competent in

- a. collecting, processing and analyzing biological specimens and other samples from a variety of sources and other substances;
- b. performing tests from a variety of sources to include body fluids, cells and other substances;
- c. recognizing factors that affect procedures and results and taking appropriate actions within predetermined limits when corrections are indicated;
- d. performing and monitoring quality control within predetermined limits;
- e. performing preventive and corrective maintenance of equipment and instruments or referring to appropriate sources for repairs;
- f. applying principles of safety;
- g. demonstrating professional conduct and interpersonal communication skills with clients, laboratory personnel, other health care professionals and the public;
- h. recognizing the responsibilities of other laboratory and health care professionals and interacting with them with respect for their jobs and patient care;
- i. applying basic scientific principles in learning new techniques and procedures;
- j. relating laboratory findings to related decision outcomes such as common disease processes;
- k. establishing and maintaining competency and continuing education as a function of growth and maintenance of professional competence.
   (Adapted from the National Accrediting Agency for Clinical Laboratory Sciences-Essentials)
- 3. Clinical Laboratory Assistant is an individual who provides service and support to the clinical laboratory science and biotechnology professionals. Specimen collection and transport, reagent and testing preparation and simple tests are performed. In laboratories accredited by the Health Care Financing Administration, the clinical laboratory assistant may qualify as testing personnel. Clinical laboratory assistants are competent in
  - a. knowledge of the health care delivery system and medical terminology;
  - b. knowledge of infection control and safety in health care settings;
  - c. knowledge of requirements for specimen collection including basic anatomy and physiology, importance of specimen collection in overall client care systems, collection equipment, various additives used, special precautions necessary and substances that can interfere in the analysis of samples;
  - d. preparation and performance of venipuncture and capillary puncture;
  - e. point-of-care testing;
  - f. vital signs evaluation;
  - g. preparation of reagents, standards and controls, according to procedure;
  - h. determining the suitability of reagents, storage requirements, standards and controls according to predetermined criteria;
  - i. preparation of specimens/samples for analysis;
  - j. labeling, transport and processing of samples;
  - k. reviewing, reporting and recording results using predetermined criteria;
  - l. understanding quality control procedures;
  - m. basic concepts of communication, personal customer interaction, stress management, professional behavior and legal implications of the workplace;
  - n. use of computer systems and applications necessary to assigned duties;
  - o. laboratory measurement;
  - accurately performing appropriate tests as limited by established regulations.
     (Adapted from the National Accrediting Agency for Clinical Laboratory Sciences-Essentials)



- 4. Phlebotomist is an individual who collects laboratory specimens by venipuncture or skin puncture to aid in the assessment of a client's medical condition. Aphlebotomist has basic understanding of human anatomy and physiology, the overall organization and operations of a laboratory, as well as in-depth knowledge of specimen collection tools and techniques. Phlebotomists are able to approach, communicate and positively interact with the client and other peer professionals while performing duties which may also involve stressful situations. Strict adherence to safety and infection control procedures is required at all times. A phlebotomist is able to assess a patient's condition and know how to obtain the specimen required while keeping the client's best interest as the primary concern. This is done without direct supervision. Knowing when to consult a supervisor for assistance in determining appropriate action is required.
- 5. Sanitarian is an individual who serves in the environmental health arena to develop, revise and implement procedures and techniques specific to health programs in areas such as milk and food protection, animal, insect and rodent control. A sanitarian applies clinical laboratory skills to inspect facilities for compliance with sanitation laws and regulations, to evaluate water supplies and sewage systems, to assist in investigation of communicable disease outbreaks implicating food or water or other environmental causes in the community and may conduct training.

#### B. Employment and Earnings Opportunities

#### 1. Education and Training Requirements

The occupations in this occupational cluster require basic workplace skills and technical training according to national data sources and industry/business leaders.

### 2. Employment Opportunities

Both nationally and in Illinois, employment of clinical laboratory workers will grow about as fast as the average for all occupations through the year 2005. Continued expansion is foreseen due to (a) the increase in disease that will accompany rapid growth of the middle-aged and older population; (b) the continued use of new and more powerful diagnostic tests; and (c) the work toward finding the cause, treatment and cure for diseases such as acquired immune deficiency syndrome (AIDS). Further advances in biotechnology will also continue to spur greater use of medical laboratory testing. However, isolating labor market information solely for the occupations of phlebotomist and sanitarian is difficult at best.

3. Earnings Opportunities	Middle Range Annual Earnings, 1996*	
Clinical Laboratory Technologists	\$30,660 - 36,500	
Clinical Laboratory Technicians	\$24,525 - 29,975	
Clinical Laboratory Assistants	\$22,620 - 40,790	
Phlebotomists	\$18,750 - 21,450	
Sanitarians	\$20,000 - 35,000	

<sup>\*</sup> Middle Range is the middle 50%, i.e., one-fourth of persons in the occupation earn below the bottom of the range and one-fourth of persons in the occupation earn above the top of the range.

Sources: 1996 Occupational Wage Survey, Illinois Department of Employment Security, Economic Information and Analysis Division; Horizons Career Information System and Allied Health and Rehabilitation Professions Education Directory '96-'97, American Medical Association. Prepared for the Illinois Occupational Skill Standards and Credentialing Council (IOSSCC) by the Illinois Occupational Information Coordinating Committee (IOICC), June 1997.



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A.	Developing an Employment Plan	1.	Match interests to employment area.
		2.	Match aptitudes to employment area.
		3.	Identify short-term work goals.
		4.	Match attitudes to job area.
			Match personality type to job area.
			Match physical capabilities to job area.
			Identify career information from counseling sources.
			Demonstrate a drug-free status.
B.	Seeking and Applying for	1.	Locate employment opportunities.
	Employment Opportunities		Identify job requirements.
			Locate resources for finding employment.
			Prepare a resume.
			Prepare for job interview.
		6.	Identify conditions for employment.
	•		Evaluate job opportunities.
			Identify steps in applying for a job.
		9	Write job application letter.
		10	Write interview follow-up letter.
			Complete job application form.
			Identify attire for job interview.
		12.	ractions attaine for job lines view.
C.	Accepting Employment	1	Apply for social security number.
			Complete state and federal tax forms.
			Accept or reject employment offer.
			Complete employee's Withholding Allowance
			Certificate Form W-4.
			October of the William
D.	Communicating on the Job	1.	Communicate orally with others.
	-		Use telephone etiquette.
			Interpret the use of body language.
			Prepare written communication.
			Follow written directions.
			Ask questions about tasks.
			1
E.	Interpreting the Economics	1.	Identify the role of business in the economic system.
	of Work		Describe responsibilities of employee.
			Describe responsibilities of employer or management.
			Investigate opportunities and options for business
	•		ownership.
		5	Assess entrepreneurship skills.
		0.	ribbeds environced ship same.
F.	Maintaining Professionalism	1	Participate in employment orientation.
			Assess business image, products and/or services.
		2.	Identify positive behavior.
			Identify company dress and appearance standards.
		ο.	Participate in meetings in a positive and constructive
		^	manner.
			Identify work-related terminology.
		7.	Identify how to treat people with respect.



	<del></del>		
G.	Adapting to and Coping		Identify elements of job transition.
	with Change	2.	Formulate a transition plan.
		3.	Identify implementation procedures for a transition plan
			Evaluate the transition plan.
			Exhibit ability to handle stress.
	•	6.	Recognize need to change or quit a job.
		7.	Write a letter of resignation.
H.	Solving Problems and	1.	Identify the problem.
	Critical Thinking		Clarify purposes and goals.
		3.	Identify solutions to a problem and their impact.
	•	4.	Employ reasoning skills.
		5.	Evaluate options.
			Set priorities.
		7.	Select and implement a solution to a problem.
		8.	Evaluate results of implemented option.
		9.	Organize workloads.
		10.	Assess employer and employee responsibility in solving a problem.
l.	Maintaining a Safe and Healthy	1	Identify safety and health rules/procedures.
	Work Environment		Demonstrate the knowledge of equipment in the
			workplace.
		3	Identify conservation and environmental practices and
		ψ.	policies.
		4.	Act during emergencies.
		5	Maintain work area.
			Identify hazardous substances in the workplace.
J.	Demonstrating Work Ethics		71
٠.	and Behavior	1.	Identify established rules, regulations and policies.
	anu benatioi		Practice cost effectiveness.
			Practice time management.
			Assume responsibility for decisions and actions.
			Exhibit pride.
		о. 7	Display initiative.
			Display assertiveness.
		o. 0	Demonstrate a willingness to learn.
		9. 10.	Identify the value of maintaining regular attendance.
		10.	Apply ethical reasoning.
<u>_</u>	Demonstrating Technological Literacy		Demonstrate basic keyboarding skills.
	Littiaty		Demonstrate basic knowledge of computing.
		ა.	Recognize impact of technological changes on tasks and people.
	Maintaining Interpersonal	1.	Value individual diversity.
	Relationships		Respond to praise or criticism.
			Provide constructive praise or criticism.
			Channel and control emotional reactions.
			Resolve conflicts.
			Display a positive attitude.
			Identify and react to sexual intimidation/harassment.
1.	Demonstrating Teamwork	1.	Identify style of leadership used in teamwork.
			Work with team members.
			Complete a team task.
			Evaluate outcomes.



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